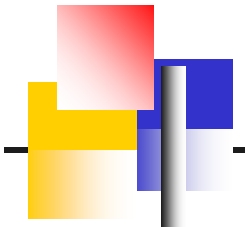
EDAN INSTRUMENTS, INC

CE 0123



Fetal & maternal Monitor

F6

User Manual

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which Edan Instruments, Inc. (hereinafter called EDAN) can not be held liable.

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The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

Using This Label Guide

This guide is designed to give key concepts on safety precautions.

⚠WARNING⚠

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

⚠CAUTION⚠

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

Revision History

Date	ECO#	Version	Description
2009/01/17	---	V1.0	1st edition
2009/08/14	ECO-F9-9003	V1.1	Corrected grammar and punctuation. Revised interface and cursor, and added archive managing, auto measuring according to the V1.4 software.

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Chapter 1 Safety Guidance

NOTES:

1) In order to ensure the operator and patient's safety, read through this chapter before using this monitor.
2) This user manual is written to cover the maximum configuration. Therefore, your model may not have some of the parameters and functions described, depending on what you have ordered.

1.1 Intended Use

The F6 Fetal & maternal Monitor (hereinafter called the monitor) is intended for non-invasive and invasive monitoring of fetus during antepartum examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

The monitor provides Non-stress testing for pregnant women from the 28th week of gestation. It can externally monitor the FHRs using ultrasound and uterine activity via a TOCO transducer. Alternatively, it can internally monitor one of the FHRs with DECG and uterine activity with an IUPC.

Contraindications: The monitor is not intended for use in intensive care units, operating rooms or for home use.

1.2 Instruction for Safe Operation

- The monitor is designed to comply with the international safety requirements IEC/EN 60601-1 for medical electrical equipment. It is class I equipment.
- The monitor operates within specifications at ambient temperatures between 5ºC (41ºF) and 40ºC (104ºF). Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5 cm) clearance around the instrument for proper air circulation.
- You must check that the equipment, cables and transducers do not have visible evidence of damage that may affect patient safety or monitoring capability before use. If damage is evident, replacement is recommended before use.
- The monitor must be serviced only by authorized and qualified personnel. The manufacturer does not accept responsibility for safety compliance, reliability and performance if modifications or repairs are carried out by unauthorized personnel. Identical replacement parts must be used.
- Perform periodic safety testing to ensure proper patient safety. This should include leakage

current measurement and insulation testing. The recommended testing interval is once per year.

- The protective categories against electric shock of the patient connections are:



1) Ultrasound (FHR1, FHR2) 2) External TOCO

3) Fetal Movement Mark (FM) 4) Fetal Stimulator (FS)

This symbol indicates that the electric shock defend grade of this instrument is Type B.



1) IUP

This symbol indicates that the electric shock defend grade of this instrument is Type BF.



1) DECG

This symbol indicates that the electric shock defend grade of this instrument is Type CF.

The monitor described in this user manual is not protected against:

a) The effects of defibrillator shocks

b) The effects of defibrillator discharge

c) The effects of high frequency currents

d) The interference of electrosurgery equipment

1.3 Ultrasound Safety Guide

Fetal Use

The monitor is designed for continuous fetal heart rate monitoring during pregnancy and labor. Clinical interpretation of fetal heart rate traces can diagnose fetal and/or maternal problems and complications.

Instructions for Use in Minimizing Patient Exposure

The acoustic output of the monitor is internally controlled and can not be varied by the operator in the course of the examination. The duration of exposure is, however, fully under the control of the operator. Mastery of the examination techniques described in the User Manual will facilitate obtaining the maximum amount of diagnostic information with the minimum amount of exposure. The exercising of clinical judgment in the monitoring of low risk patients will avoid unnecessary insonation.

1.4 Safety Precautions

WARNING and **CAUTION** messages must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the instrument.

⚠WARNING⚠:

For using safety:

1) The monitor is provided for the use of qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.
2) Only qualified service engineers can install this equipment. Only service engineers authorized by the manufacturer can open the shell.
3) This device is not intended for home use.
4) **EXPLOSION HAZARD** - Do not use the F6 monitor in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
5) **SHOCK HAZARD** - the power receptacle must be a three-wire grounded outlet. A hospital grade outlet is required. Never adapt the three-prong plug from the monitor to fit a two-slot outlet. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the monitor.
6) Do not apply this monitor and other ultrasonic equipment simultaneously on a same patient, in case of possible hazard caused by leakage current superposition.
7) Do not apply this monitor simultaneously with other PATIENT-connected equipment, such as, a cardiac pacemaker or other electrical stimulators, on a same patient.
8) Do not switch on device power until all cables have been properly connected and verified.
9) Do not touch signal input or output connector and the patient simultaneously.
10) Equipment and devices that connect to the monitor should form an equipotential body to ensure effective grounding.
11) Disconnect power cord before changing fuses. Replace them with those of the same specifications only.
12) **SHOCK HAZARD** - Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.
13) **SHOCK HAZARD** - Do not remove the top panel cover during operation or while power is connected. Only authorized service personnel could remove the unit cover.
14) The monitor is not protected against defibrillation. Do not apply it during electro-surgery or MRI; otherwise it might result in harming the patient or the operator.
15) Only connect accessories supplied or recommended by the manufacturer to the device.

16) Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Anybody who connects additional equipment to the signal input connector or signal output connector to configure a medical system must ensure that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.

For proper monitoring:

17) This device is not intended for treatment.

18) The fetal spiral electrode and intrauterine pressure catheter are disposable. Discard them after use.

19) The IUPC is neither intended nor approved for measuring intrauterine pressure extraovularly; attempting to do so may lead to maternal discomfort or injury.

20) Alarms must be set up according to different situations of patients. Make sure that audio sounds can be activated when an alarm occurs.

For using the battery:

21) Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the user manual and safety precautions thoroughly.

22) Do not connect the battery cable connector or battery socket with metal objects, which can result in short circuit.

23) Do not unplug the battery when monitoring.

24) Do not heat or throw the battery into a fire.

25) Do not use or leave battery close to fire or other places where the temperature may be above 60 ºC (140 ºF).

26) Do not immerse, throw, or wet the battery in water/ seawater.

27) Do not destroy the battery: Do not pierce battery with a sharp object such as a needle; do not hit with a hammer, step on or throw or drop to cause strong shock; Do not disassemble or modify the battery.

28) Use the battery only in the F6 Monitor. Do not connect battery directly to an electric outlet or cigarette lighter charger.

29) If the liquid leak from the battery gets into eyes, do not rub the eyes. Wash them well with clean water and see a doctor immediately.

30) Do not solder the leading wire and the battery terminal directly.

31) If the liquid leak from the battery spills onto your skin or clothes, wash well with fresh water immediately.

32) Keep away from fire immediately when leakage or foul odor is detected.

33) Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the monitor.

34) Do not use a battery with serious scar or deformation.

CAUTION:

1) Federal (U.S.) law restricts this device to sale by or on the order of a physician.

2) Refer servicing to qualified personnel.

3) The device is designed for continuous operation and is “ordinary” (i.e. not drip or splash-proof).

4) Keep the environment clean. Avoid vibration. Keep it far from corrosive medicine, dust area, high-temperature and humid environment.

5) When installing the unit into a cabinet, allow for adequate ventilation, accessibility for servicing, and room for adequate visualization and operation.

6) Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

7) Sterility can not be guaranteed if package of the fetal spiral electrode is broken or opened.

8) The fetal spiral electrode has been sterilized by gamma radiation. Do not re-sterilize.

9) Do not sterilize the monitor or any accessory with autoclave or gas.

10) Switch off the system power before cleaning. Cleaning consists of removing all dust from the exterior surface of the equipment with a soft brush or cloth. Use a brush to dislodge any dirt on or around the connectors and panel edges. Remove dirt with a soft cloth, slightly dampened with a mild detergent solution or 70% ethanol or isopropranol.

11) When washing the belts, the water temperature must not exceed 60 ºC (140 ºF).

12) **Electromagnetic Interference** - Ensure that the environment in which the F6 monitor is installed is not subject to any source of strong electromagnetic interference, such as CT, radio transmitters, mobile phone base stations, etc.

13) Do not use mobile phones nearby in the process of monitoring.

14) The device and reusable accessories could be sent back to the manufacturer for recycling or proper disposal after their useful lives.

15) While the battery is charged, used or stored, keep it away from objects or materials with static electric charges.

16) If the terminals of the battery become dirty, wipe with a dry cloth before using the battery.

17) The recommended charge temperature range is from 0 ºC (32 ºF) to 40 ºC (104 ºF). Do not exceed this range.

18) Batteries have life cycles. If the time that the monitor uses the battery becomes much shorter than usual, the battery life is at an end. Replace the battery with a new one the same as the one provided or recommended by the manufacturer.

19) When not using battery for an extended period, remove it from the monitor and store it in a place with low humidity and low temperature.

20) Remove a battery whose life cycle has expired from the monitor immediately.

21) For information on installing and removing the battery from the monitor, thoroughly read the user manual.

22) The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.

23) The useful life of the monitor is 5 years, dating from the manufacturing date marked on the bottom panel label.

24) The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.

1.5 Definitions and Symbols



Socket for ultrasound transducer 1 (Type B applied part)



Socket for ultrasound transducer 2 (Type B applied part)



Socket for DECG cable (Type CF applied part)



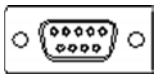
Socket for TOCO transducer (Type B applied part) or IUP cable (Type BF applied part)



Socket for Remote Event Marker (Type B applied part)



Socket for Fetal Stimulator (Type B applied part)



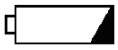
DB9 Interface



RJ45 Interface



Equipotential Grounding System



Charge Indicator



Alternating Current (a.c.)



Stand-by



Attention, Consult Accompanying Documents



Type B Applied Part Symbol



Type BF Applied Part Symbol



Type CF Applied Part Symbol



The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.



The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.



The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life and that this unit was put on the market after 13 August 2005.

P/N	Part Number
SN	Serial Number
	Date Of Manufacture
	Manufacturer
EC REP	Authorized Representative in the European Community
	Recycle
Rx only (U.S.)	Federal (U.S.) Law restricts this device to sale by or on the order of a physician

Chapter 2 Installation Guidance

NOTE: Installation must be carried out by qualified personnel authorized by the manufacturer.

2.1 Opening and Checking Package

Open the package; take out the monitor and accessories carefully. Keep the package for possible future transportation or storage. Check the components according to the packing list.

- Check for any mechanical damage.
- Check all the cables and accessories.

If there is any problem, contact us or your local distributor immediately.

2.2 Installing Battery

⚠**WARNING**⚠**:** Switch off the monitor and unplug the power cord before installing or removing the battery.

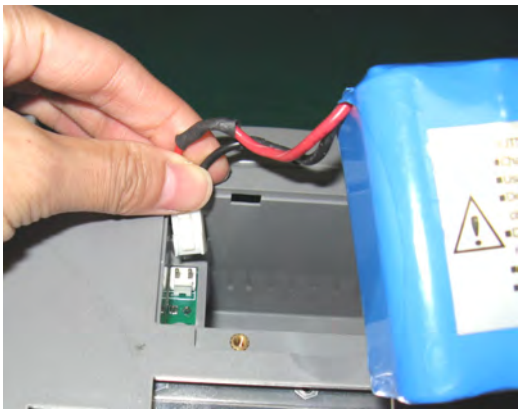
If your monitor has configured the rechargeable lithium-ion battery, follow these steps to install the battery:

(1) Battery Installation

1) Carefully place the monitor upside down on a flat surface covered with cloth or other type of protecting pad.
2) Remove the screws of the battery compartment using a cross-head screw driver. Remove the battery compartment cover.

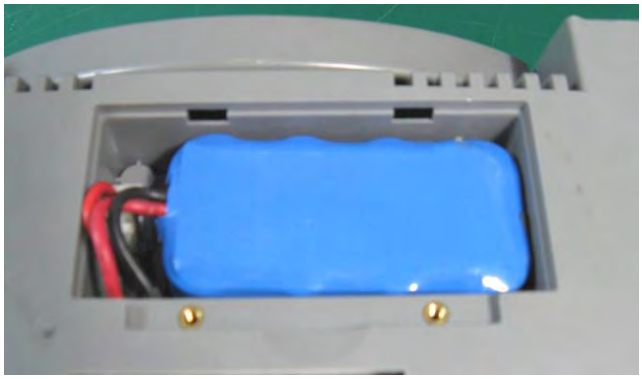


3) Take the battery out from package. Place the battery into the compartment with the wired direction on the outside.
4) Insert the cable connector into the socket.



5) Put the battery and the cables into the battery compartment.





6) Shut the battery compartment cover and fix the screws.



(2) Battery Removal

Fold the LCD display completely flat before turning the monitor upside down. Remove the battery in reverse order.

NOTES:

1) If a rechargeable battery is outfitted, charge it fully each time after using the device to ensure the electric power is enough.

2) When the battery configuration is provided, after the device is transported or stored, the battery must be charged. Connecting to power supply will charge the battery no matter if the monitor is powered on.

2.3 Installing Monitor

The monitor can be placed on a flat surface, or be installed on a wall or a trolley. The service engineer should install the monitor properly.

2.4 Connecting Power Cable

- Make sure the AC power supply of the monitor complies with the following specification: 100V-240V~, 50Hz/60 Hz.
- Apply the power cable provided with the monitor. Plug one end of the power cable to the power socket of the monitor. Connect the other end to a grounded 3-phase power output special for hospital usage.

⚠**WARNING**⚠**:** If the protective grounding (protective earth) system is doubtful, the power of the monitor must be supplied by inner power only.

Chapter 3 Monitor and Accessories

3.1 Configuration

The standard configuration of F6 monitor includes FHR1 (fetal heart rate 1), FHR2 (fetal heart rate 2), TOCO, MFM and AFM monitoring.

That is to say, F6 = FHR1+ FHR2+ TOCO + MFM + AFM

Optionally you can add DECG module to F6, providing DFHR (direct fetal heart rate) and IUP (Intra-uterine Pressure) monitoring.

That is to say, F6_optional = F6 + DFHR + IUP

A fetal stimulator can be provided to give a mild vibrating stimulation to the fetus. Refer to *FS-1 Fetal Stimulator User Manua*l for details.

A DB9 interface and an RJ45 interface are built in the monitor. With them, F6 monitor can be connected to a computer or the MFM-CNS central monitoring system via 485 network or Ethernet. Optionally, you can order a built-in wireless network module to connect the monitor via wireless network.

F6 monitor adopts a 10.2” LCD, on which the collected data, traces, and numerics are displayed. The built-in thermal recorder prints the fetal traces. Rechargeable lithium-ion battery is provided for options.

3.2 Overview

NOTE: The pictures and interfaces in this manual are for reference only.



1 Keys
2 Transducer
3 Sockets
4 Alarm Indicator
5 Display Screen
6 Control Knob
7 Charge, AC, Power Indicator
8 Paper Drawer

Figure 3-1 F6 Appearance (for reference only)

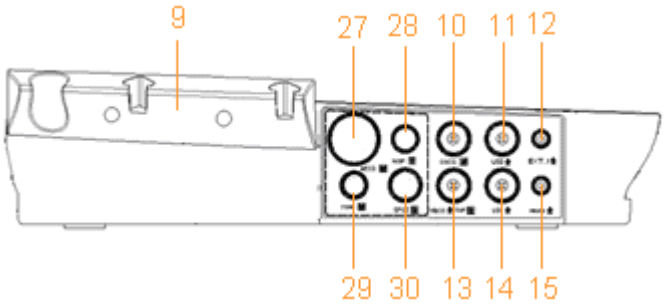


Figure 3-2 Left Panel

9 Transducer Holder
10 DECG Socket
11 US2 Socket
12 EXT.1 Socket
13 TOCO/IUP Socket
14 US1 Socket
15 MARK Socket
27, 28, 29, 30 Reserved

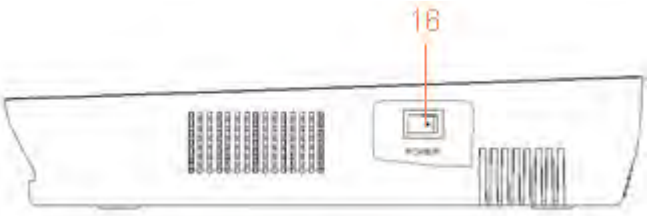


Figure 3-3 Right Panel

16 POWER Switch

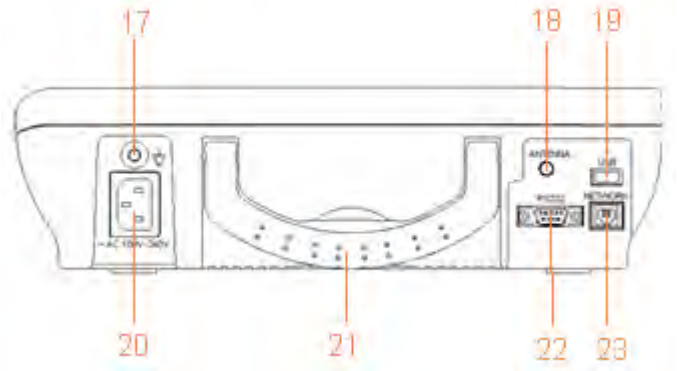


Figure 3-4 Rear Panel

17 Equipotential Grounding Terminal
18 Antenna
19 USB Socket
20 Power Socket
21 Handle
22 DB9 Socket
23 RJ45Socket

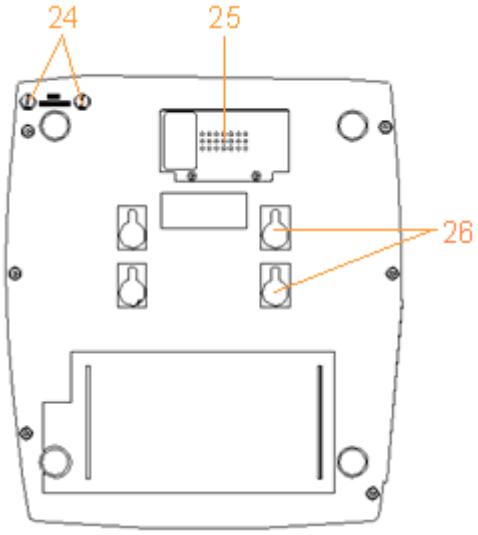
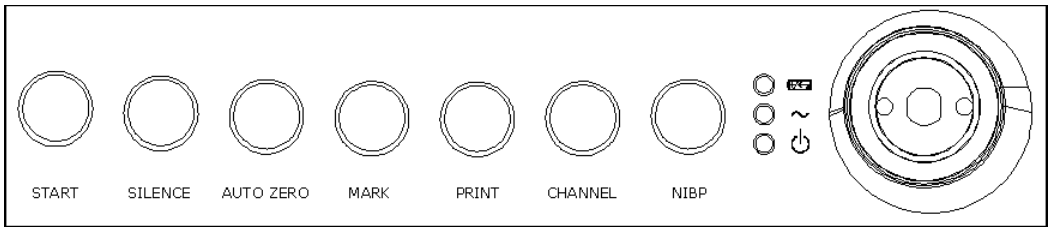


Figure 3-5 Bottom Panel

24 Fuses
25 Battery Compartment
26 Wall-mounting Holes

3.2.1 Keys and Control Knob

Figure 3-6 Keys and Control Knob



The Monitor is a user-friendly device with operation conducted by a few keys on the front panel and the control knob. Their functions are as follows:

(1) START

Function: Start monitoring and move back

Press this key to start monitoring (under the monitoring status) or move back to the previous interface (under the login status or setting status).

(2) SILENCE

Function: Switch on/Switch off audible alarm

Press this key to switch on or off the audible alarm.

(3) AUTO ZERO

Function: TOCO zero

Adjust the external TOCO contractions trace/value to preset unit (external monitoring contractions) or the IUP trace/value to reference point 0 (internal monitoring contractions).

(4) MARK

Function: Record an event.

Press this key to make an event mark.

(5) PRINT

Function: Start / stop printing

Press this key to toggle between starting and stopping printing.

(6) CHANNEL

Function: Switch the channels

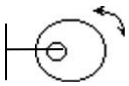
Press this key to toggle the FH sound between US1 channel and US2 channel.

(7) NIBP

Function: Start or stop a NIBP measurement.

Reserved.

(8) CONTROL KNOB

Press Control Knob  Rotate Control Knob

Function: Adjust volume, setup, login and review control.

It can be pressed like other keys and be rotated clockwise or counterclockwise. All the operations on the screen or in the menu are completed by using the control knob.

The highlighted rectangular mark on the screen that moves with the rotation of the control knob is called “cursor”. Operations can be performed in the position on the screen where the cursor stays. When the cursor is located on a certain item, you can press the control knob to open its submenu or confirm the operation. Press the control knob again, and the cursor will be able to move around on the interface/menus.

Operation Procedure:

a) Rotate the control knob to move the cursor to the item you want;

b) Press the control knob;

c) One of the following three results will be achieved:

- A menu pops up on the screen, or the menu is replaced by a new one;
- The cursor pane turns into broken line pane and the background turns into blue, the content in the pane can be changed while rotating the control knob. At this time, rotate the knob until the needed item appears; press the knob to confirm selection.
- The function operates immediately.

NOTE: The word “select” hereinafter stands for rotating the control knob cursor to an item then pressing the knob.

CAUTION: This monitor is a normal medical device. Please avoid violent operations such as continuously pressing the keys or control knob.

3.2.2 Indicators

There are four groups of indicator on top of the screen and the front panel. From the top down they are: alarm indicator, CHARGE indicator, AC indicator and Power indicator. Table 3-1 lists their meanings:

Table 3-1 Indicator description

Indicator	Status of Indicator	Meaning
Alarm Indicator	Orange flash or light	An alarm is active.
	Off	No alarm is active.

Charge Indicator	On	The battery is being charged.
	Off	No battery is loaded or the battery is fully charged.
AC Indicator	On	The monitor is connected to AC power supply.
	Off	The monitor is not connected to AC power supply.
Power Indicator	On	The monitor is powered on.
	Off	The monitor is powered off.

3.3 Accessories

3.3.1 Transducers

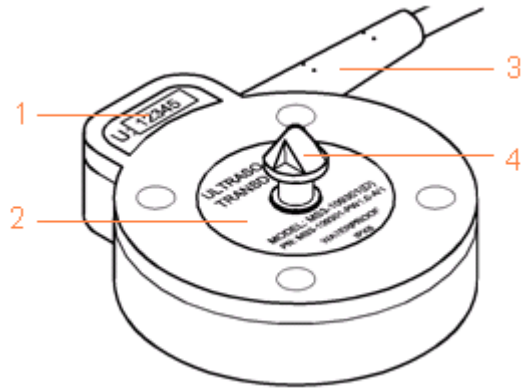


Figure 3-7 Ultrasound (US) transducer

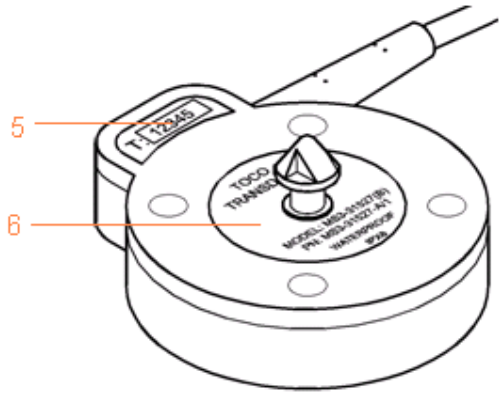


Figure 3-8 TOCO transducer

1 Serial number label of the US transducer, pink. U:xxxxx is the serial number.

2 Specification label of the US transducer, pink.

3 Transducer cable

4 Belt buckle

5 Serial number label of the TOCO transducer, blue. T:xxxxx is the serial number.

6 Specification label of the TOCO transducer, blue.

Information on the specification label includes:

PN: MS3-109301: Part number of this US transducer.

PN: MS3-31527: Part number of this TOCO transducer.

PW 1.0: pulsed wave, the central frequency of the US transducer is 1.0 MHz.

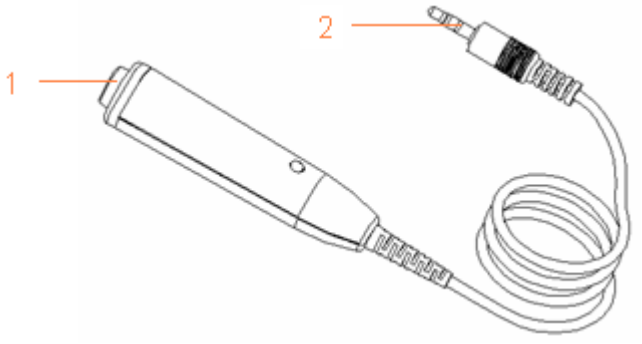
A/1: Version number of the transducer.

WATERPROOF: means the transducer is waterproof.

IPX8: means the transducer can work continuously for 5 hours under 1-metre water without being waterlogged.

CAUTION: The waterproof parts of the US/TOCO transducer are restricted to the main body and the cable. Do not immerse the plug into any liquid in the process of monitoring or cleaning.

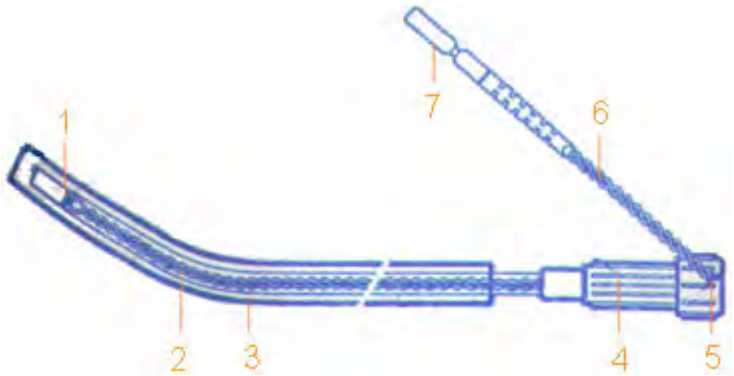
3.3.2 Remote Event Marker



1 Key of the remote event marker
2 Plug of the remote event marker

Figure 3-9 Remote Event Marker

3.3.3 Fetal Spiral Electrode



1 Reference Electrode
2 Drive Tube
3 Guide Tube
4 Drive Handle
5 Handle Notch
6 Electrode Wire
7 Safety Cap

Figure 3-10 Fetal Spiral Electrode

3.3.4 Fetal Stimulator

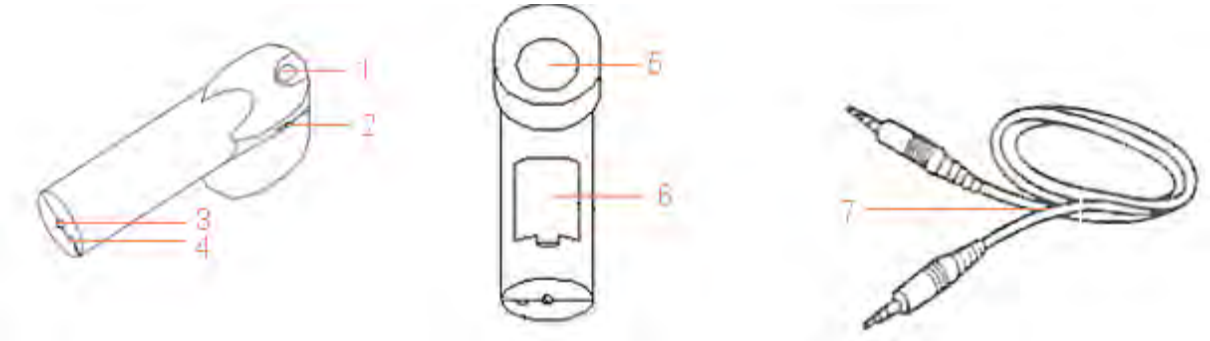


Figure 3-11 Operating control of fetal stimulator

1	Operating Switch	2	Vibration Rhythm Adjusting Wheel
3	Marker Socket	4	Mode Selecting Switch
5	Vibrating Head	6	Battery Compartment
7	Audio Cable		

3.4 Screen

3.4.1 Main Interface



Figure 3-12 Main Interface

The main interface of the monitor displays numbers, traces, menus and monitor status information. The screen background color has four choices: black (default), green, orange and blue.

To change the screen color,

1 Select setup key  on the main interface.
2 Select **General** > **Screen Color**.
3 Select the required color.
4 Select **OK**.

According to the content, the main interface is divided into four windows: (1) Message Window (2) Trace/ Menu Window (3) Numeric Window (4) Status Window.

(1) Message Window



a) 

:

Alarm messages displaying area. When an alarm is active, the message will be displayed here in yellow. Patient alarms will be displayed on the left and technical alarms in the center.

b)  : **Alarm reviewing key.** Select this key to open the alarm reviewing menu.

c)  : **Mat. Info key.** Select this key to open maternal information menu for inputting or changing the patient's ID and name.

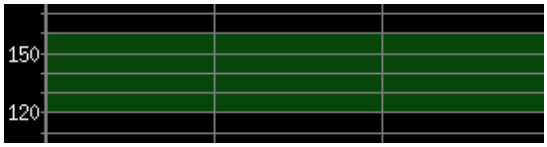
d)  : **Setup key.** Select this key to open setup main menu.

(2) Trace/Menu Window

The trace/menu window occupies most space of the screen. During monitoring or reviewing, it displays traces; during setting, it displays setup menus.

The background pane bar supports two standards: 30 ~ 240 (American standard) and 50 ~ 210 (International standard).

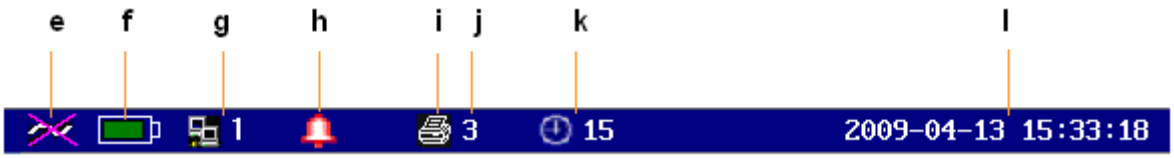
The 120 ~ 160 bmp area with the green band in between the fetal heart rate pane makes it easy to observe if the FHR exceeds this range. So you can easily tell if the fetal heart rate is too low or too high.



(3) Numeric Window

The fetal monitoring numerics are displayed here.

(4) Status Window



e) Power indicator

 - AC power supplied.

 - no AC power supplied.

f) Battery indicator

 - battery is loaded; the green pane indicates the charge of the battery.

 - no battery is loaded.

g) Network connection indicator and device no.

 - the monitor is online.

 - the monitor is offline.

NOTE: The network connection indicator is not available if the net version is Insight or Philips.

h) Audio alarm indicator

 - the audible alarm is switched on.

 - the audible alarm is switched off.

i) Recorder status indicator

 - the recorder is in the process of printing.

 - no printing is going on.

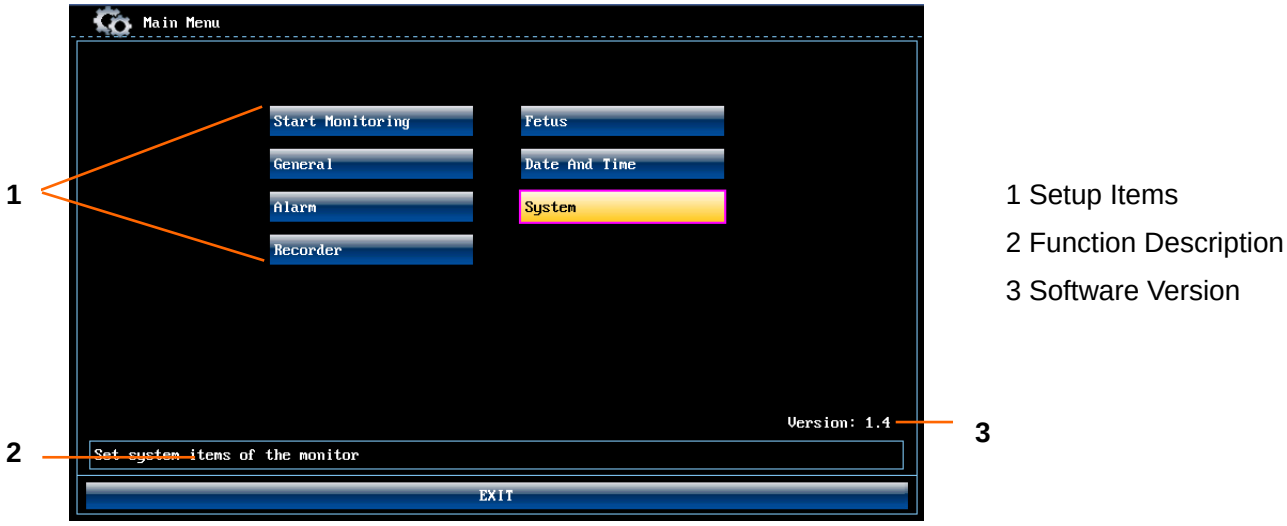
j)  - Print speed.

k)  - Print remaining time.

l) The date and time of the monitor.

3.4.2 Setup Interface

The setup menu is provided to change the monitor configurations and monitoring settings. Press the Setup key  on the main interface to open this menu.



1 Setup Items

2 Function Description

3 Software Version

In the setup main menu, you have access to all the items other than **System**. You can select **EXIT** to exit from this menu.

The items in this main menu all have submenu(s). To confirm the setting changes in the submenus, you need to select **OK** to exit. If you don't want to store the new settings, select **Cancel**, or press the **START** key to return to the main interface. If no operation is performed in 30 seconds, the menu will return to the upper directory. The change will not be stored.

Once you select **OK** to confirm the setting changes, the new settings will be stored in the monitor's long-term memory. If the monitor is switched on again after being switched off or a power loss, it will restore the new settings.

For your reference, when the cursor is located at an item in this menu, the monitor provides a brief function description of this item in a pane with blue frame under the items. For example, the cursor is located at "System" in the illustration above. Correspondingly, its function "Set system items of the monitor" is issued in the blue frame pane.

3.5 Ordering Information

Accessories supplied or approved by EDAN can be used with the F6 monitor. See the following table for details. The accessories employed by us, such as the rechargeable battery (model No.: HYLB) manufactured by HENGYU are products having passed the authentication of CE, and they have the characteristics specified by their manufacturers.

Accessory (Spare Part)	**Part Number**
Ultrasound Transducer	MS3-109301
TOCO Transducer	MS3-31527
Remote Event Marker	MS3-31112
Belt	MS1-02264
Aquasonic Coupling Gel (0.25ltr bottle)	M50-78001
Fetal Stimulator	MS9-17660
DECG Cable	MS2-02148
Disposable Fetal Spiral Electrode	MS0-02145
Disposable Maternal Attachment Pad Electrode	MS0-02146
Intrauterine Pressure Connecting Cable	MS1R-107796
Intrauterine Pressure Cable	MS1-104152
Disposable Intrauterine Pressure Catheter	MS1-104153
Thermosensitive Paper (GE-American)	M25R-75111

Thermosensitive Paper (GE-International)	M25R-75112
Thermosensitive Paper (Philips-American)	M25R-75113
Thermosensitive Paper (Philips-International)	M25R-75114
Fuse T1.6AL 250V	M21-64010
Rechargeable Lithium-ion Battery	M21R-064118

⚠**CAUTION**⚠**:** Only connect the accessories supplied or recommended by the manufacturer to the monitor.

Chapter 4 Alarms

4.1 Alarms Classification

The monitor has two types of alarm: patient alarm and technical alarm.

Patient alarms indicate the situation of vital sign exceeding its configured limit. They can be disabled. The adjustable alarm limits determine the conditions that trigger the alarm.

Technical alarms indicate that the monitor can not measure and therefore can not detect critical patient conditions reliably. When a patient alarm is switched off, the technical alarms relative to it will be disabled as well.

The alarms have two levels: middle and low. Middle level alarm is a serious warning, whose symbol is **; low level alarm is a general warning.

The middle level alarms have higher priority than the low level alarms. If both types of alarms are active at the same time, the monitor sounds an audible indicator for the middle level alarms.

The system sets all patient alarms as middle level and all technical alarms as low level, and you can not change them.

4.2 Audible Alarm

When an alarm is active, the monitor gives out an alarm sound (the sound pressure range is 45dB ~ 85dB).

Middle level alarm: a “Do” tone is repeated three times, followed by a pause.

Low level alarm: a “Do” tone is issued, followed by a pause.

Press the **SILENCE** key on the front panel to toggle between audible alarm on and off. Meanwhile, the audible alarm indicator on the main interface will toggle between  and  . However, the alarm messages will still be displayed and the alarm indicator will still be lighted up when an alarm is active.

⚠**WARNING**⚠**:** Do not disable the audible alarm for the condition where the patient’s safety may be endangered.

4.3 Visual Alarm

When an alarm is active,

- **Alarm indicator:** the alarm indicator flashes in orange with a frequency of 0.5Hz if it is a medium level alarm; the alarm indicator lights up continuously in orange if it is a low level alarm.

- **Alarm message:** the alarm message appears in the message window of the main interface in yellow, with patient alarms on the left and technical alarms in the middle.

- **Flashing numeric:** the numeric of the measurement flashes in grey with a frequency of 2Hz.

When more than one alarm is active, the alarm messages appear in the same area in succession.

The patient alarm messages are displayed either:

- in text form, for example "** FHR2 LOW"; or
- in numeric form, for example "** FHR2 115 < 120"; ** indicates this is a medium level alarm event; the first number is the current measurement result; the second number is the preset alarm limit.

The technical alarm messages are displayed in text form, for example "Fetus EQUIP MALF".

4.4 Choosing Alarm Display Form

You can change the patient alarm display form,

1 Select setup key  on the main interface.
2 Select **Alarm > Message Form**.
3 Select **Text** (default) or **Numeric**.
4 Select **OK**.

4.5 Changing Alarm Volume

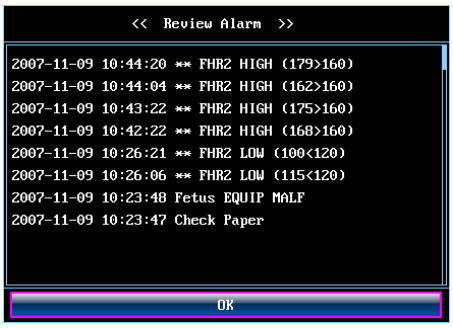
You can change the alarm volume,

1 Select setup key  on the main interface.
2 Select **Alarm > Alarm Volume**.
3 Select **Low** (default), **Medium** or **High**.
4 Select **OK**.

4.6 Reviewing Alarms

An alarm reviewing menu records a list of up to 50 of the most recent patient and technical alarm messages with date and time information.

Select the alarm reviewing key  in the message window to open this menu.



Each page displays 10 alarm records. The page mark “1/5” informs you that there are 5 pages and the present one is page 1.

You can select the alarms list and then rotate the control knob to review more alarms.

4.7 Alarm Treatment Measures

When the monitor gives out an alarm and catches your attention, you should:

- Check the patient’s condition.
- Identify the cause of the alarm.
- Silence the alarm if necessary.
- Check if the alarm is terminated when the alarm condition is solved.

4.8 Testing Alarms

To test the functions of visible and audible alarms, do the following:

1 Switch on the monitor.
2 Enable the alarm.
3 Set the alarm limits to a small range.
4 Stimulate a signal that is higher than the upper limit or lower than the lower limit. Or disconnect one of the plugs.
5 Verify if the visible and audible alarms are working properly.

4.9 Patient Alarm Defaults

Alarm Setting	Options	Default
FHR1/FHR2 Alarm	On, Off	On
FHR1/FHR2 Lower Limit	50 ~ 205 bpm, in increments of 5	120 bpm
FHR1/FHR2 Upper Limit	55 ~ 210 bpm, in increments of 5	160 bpm
FHR1/FHR2 Alarm Delay	0 ~ 300 second(s), in increments of 5	10 seconds
FHR1/FHR2 Alarm Level	Medium, not adjustable	Medium

NOTE: The upper limit must be higher than the lower limit. When setting the upper limit, you do not have access to the options that are lower than the preset lower limit, and vice versa.

Chapter 5 Printing

5.1 Function Description

The built-in thermal recorder applied in the monitor supports both the American and international standard wide recorder paper. It prints continuous traces synchronously along with marks.

The monitor supports some other functions listed below:

- **Auto start printing:** If the function is enabled, the recorder starts printing automatically when a new monitoring starts (the **START** key is pressed). Otherwise you have to press the **PRINT** key to start printing.
- **Printing timer:** The printing timer determines the elapsed time for each print. This time is adjustable. Refer to *5.2.3 Changing the Print Timer*.
- **Remaining time indicating:** A print remaining time  appears in the status window, unless the timer is set as **Infinite** or **Present ID**.
- **Fast printing:** The recorder prints the data saved in the monitor at a high speed (up to 25mm/s).
- **Data Caching:** When the paper drawer is run out of paper or when it is open, the recorder stops printing. The data from this time on (at most 60 minutes) will be temporarily saved in the internal memory. When new paper is loaded and/or the drawer is closed, the saved data will be printed out at a high speed. When the saved trace has been printed out, the recorder switches back to continue printing the current data at the normal speed automatically.

  NOTE: When the monitor is switched off, the data in the internal memory will be lost.
- **FHR2 offset:** You can set the offset of the FHR2 trace to separate the two FH traces on the screen and the recorder paper. Refer to *8.4.4 Changing FHR2/DFHR Offset.*
- **Print self-check:** The recorder prints a baseline for self checking when the monitor is switched on.

5.2 Printing Configuration

⚠**CAUTION**⚠**:** All the parameters should be well configured before printing starts. You can not change the configuration in the process of printing.

5.2.1 Switching Auto Start Printing On or Off

You can switch auto start printing on or off:

1 Select setup key  on the main interface.

2 Select **Start Monitor** > **Printing**.
3 Select **ON** or **OFF** (default).
4 Select **OK**.

5.2.2 Choosing Paper Speed

You can choose a paper speed of 1 cm/min, 2cm/min or 3cm/min:

1 Select setup key  on the main interface.
2 Select **Recorder** > **Print Speed**.
3 Select **1 cm/min**, **2 cm/min** or **3 cm/min** (default).
4 Select **OK**.

5.2.3 Changing Print Timer

You can choose different time length for the print timer:

1 Select setup key  on the main interface.
2 Select **Recorder** > **Timer**.
3 Set timer to **Infinite** (default), **Present ID** or **10 ~ 90** (minutes, the step is 5). **Infinite** means the recorder will not stop printing until the **PRINT** key is pressed. **Present ID** means the recorder will only print the traces for the patient with the present ID. It will stop when her traces come to the end. If the current page of the screen display includes more than one patient, traces of the one on the right end of the page will be the printed.
4 Select **OK**.

5.2.4 Switching Print Self-Check On or Off

You can switch print self-check on or off:

1 Select setup key  on the main interface.
2 Select **Recorder** > **Print Self-Check**.
3 Select **ON** or **OFF** (default).
4 Select **OK**.

5.3 Understanding Recorder Paper Printout

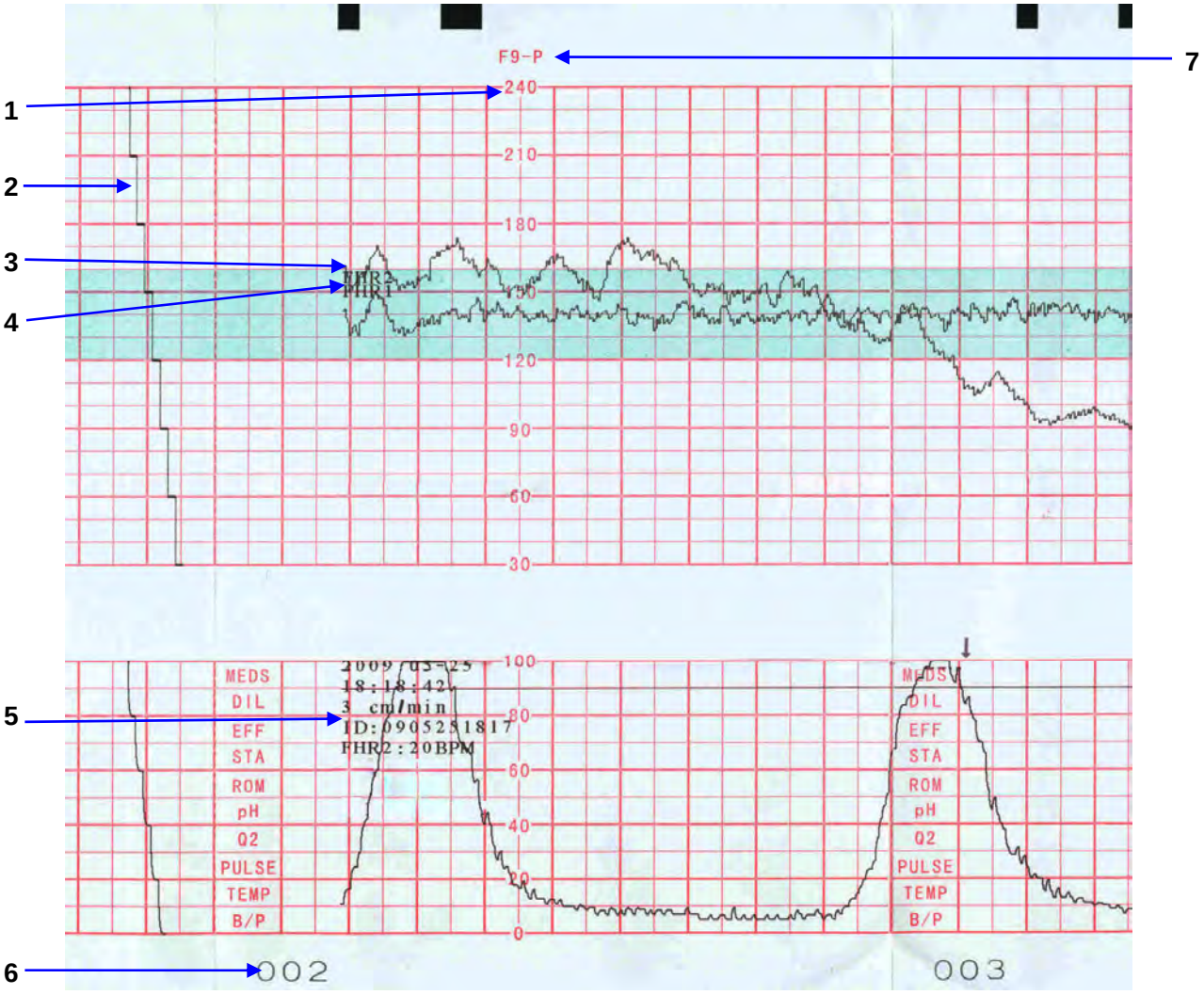
WARNING:

1) If there is any difference between the display and the printout, take the printout as criterion.

2) If the data is doubtful, clinicians should make diagnoses based on the real condition.

Figure 5-1 is an example of the recorder paper with traces. Comparing it with the monitor screen, you can find this extra information on it:

Figure 5-1 An Example of recorder paper with traces



Item	Information	Description
1	Paper Style	The FHR pane range 30 bpm ~ 240 bpm indicates the paper style is American Standard. The FHR pane range 50 bpm ~ 210 bpm indicates the paper style is International Standard.
2	Self-Check Trace	The monitor prints a self-check trace after being switched on. It is used to check if the recorder paper is properly loaded.
3	FHR2 Mark	The trace marked with “FHR2” is the FHR2 trace.
4	FHR1 Mark	The trace marked with “FHR1” is the FHR1 trace.

5	Trace Information List	A list of current date, time, print speed, ID and FHR2 offset is printed at the start of the monitoring and every ten minutes afterwards.
6	Page Mark	Each recorder paper pack has 150 pages. When you notice the page mark comes to the end, remember to load new paper in time.
7	Paper vendor	“F9-G” indicates the paper vendor is GE. “F9-P” indicates the paper vendor is Philips.

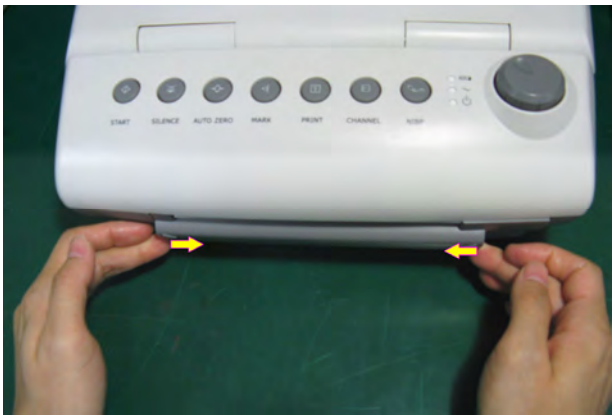
Chapter 6 Pre-Monitoring Preparation

6.1 Loading Recorder paper

⚠**CAUTION**⚠**:** Only use the recorder paper provided by the manufacturer, otherwise the recorder may be damaged. This kind of damage is not covered by warranty.

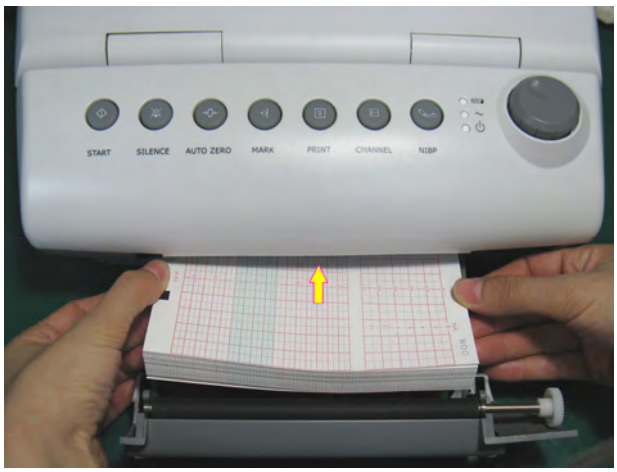
If the monitor is used for the first time or when the paper runs out, you should load paper.

1) Press the two latches on each side of the paper drawer at the same tine and slide the drawer out carefully.

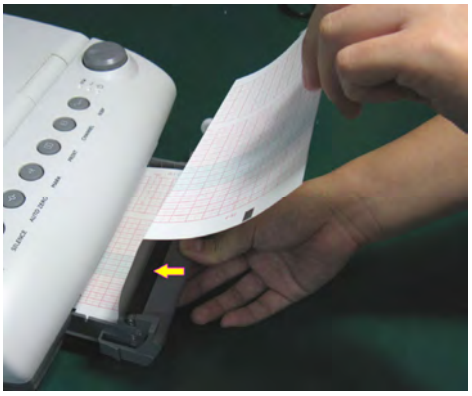


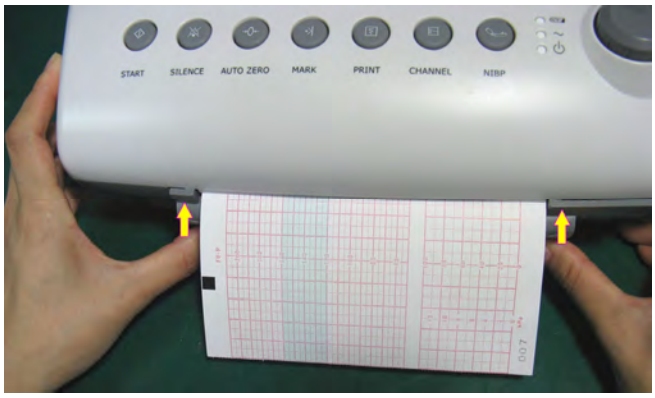


2) Take out the Z-fold thermosensitive paper and remove the wrapper.
3) Place the pack in the drawer, with the pane facing up and the green safety area on the left.



4) Unfold two sheets from the top of the pack and pull the end of the paper out of the drawer (make sure the pack in the drawer remains flat).
5) Slide the drawer in until both the latches are locked.





NOTES:

1) Be careful when inserting paper. Avoid damaging the thermosensitive print head.
2) Make sure the paper is evenly loaded in the drawer. Otherwise the data will be inaccurate or paper jam will happen.
3) Only use the paper the manufacturer approved to avoid poor printing quality, deflection, or paper jam.
4) Keep the drawer closed unless when loading paper or servicing.

Removing Paper Jam

When the recorder does not function or sound properly, open the drawer to check for a paper jam. Remove the paper jam in this way:

- Cut the recorder paper from the paper drawer edge.
- Through the hole on the bottom panel of the paper drawer, push the recorder paper up with one finger. Remove the paper.
- Reload paper and then close the drawer.



6.2 Switching On

⚠WARNING⚠:

1) Check if all the metal parts are linked to the protective earth cord and the cord is working well before powering on the monitor.
2) If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact biomedical engineer in the hospital or our service engineer immediately.

Press the **POWER** switch on the right panel to switch on the monitor. The power indicator lights up and a start-up music will be heard. You can operate the monitor after the main interface appears.

You can choose to switch the start-up music on or off,

1 Select setup key  on the main interface.
2 Select **General** > **Start-up Music**.
3 Select **ON** (default) or **OFF**.
4 Select **OK**.

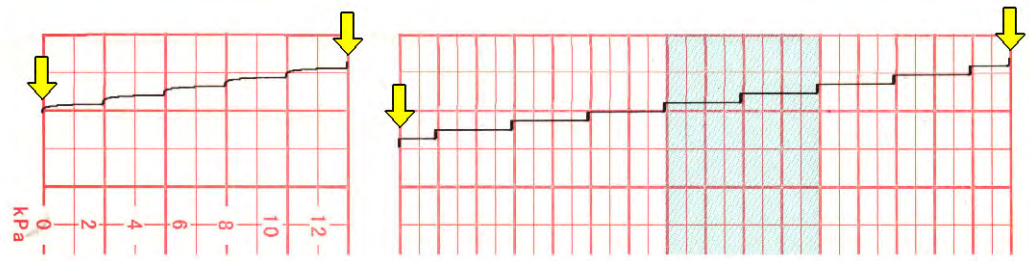
NOTES:

1) Check all the functions to make sure that the monitor is in good condition.
2) If the monitor has a great amount of data saved in its long-term memory, it will take a few seconds to load them after start-up. When you notice the message “Loading data, please wait…..” on the screen, do not operate the monitor until the main interface appears. The message “Load failed!” indicates that the data have been damaged and therefore can not be loaded.

6.3 Checking Recorder Paper

The monitor provides the print self-check function to check if the recorder paper is correctly loaded and set.

The recorder prints a baseline after start-up (if **Print Self-Check** in the menu is ON). Observe the starts and ends of the printed baselines (illustrated with the arrow). The starts and ends should be printed exactly on the edges of the pane if the recorder paper is correctly loaded and set. If they do not comply with the edges, reload paper or ask the service engineer to check the paper settings of the monitor.



If the monitor does not print the baseline, switch on the Print Self-Check and then restart the monitor.

NOTE: Make sure the paper is correctly loaded before starting printing.

6.4 Adjusting Screen Angle

The angle between the screen and the top cover of the monitor is adjustable as needed, allowing it to be mounted on a wall or placed on a flat surface.

Adjustment method:

Push the hook on top of the screen left to spring it open. Pull the screen forward to adjust to the preset screen angles of 31, 44 or 53 degrees.





To bring the screen back to flat, pull it all the way forward and then push it back.





6.5 Setting Date and Time

You can change the date and time of the monitor,

1 Select setup key  on the main interface.
2 Select **Date and Time**.
3 Set the year, month, date, hour, minute and second. The first three numbers are used to set the year, month and date. Their orders vary with the preset Date Format below.
4 Select **Date Format** for the format of the date; there are three options: yyyy-mm-dd (default), mm/dd/yyyy and dd/mm/yyyy.
5 Select **OK**.

NOTE: The date and time remain in the monitor for at least two months after it is switched off. You do not have to set date and time before monitoring each time.

6.6 Connecting Transducers

Check for visible damages of the transducers every time before connecting them to the monitor. Pay special attention to the cracks on the transducers and cables before immersing them into conductive fluid. If damage is found, replace them with good ones at once.

When plugging transducers into the monitor, make sure the arrow symbol of the connector is facing up, refer to figure 6-1.

Figure 6-1 Connecting the transducer

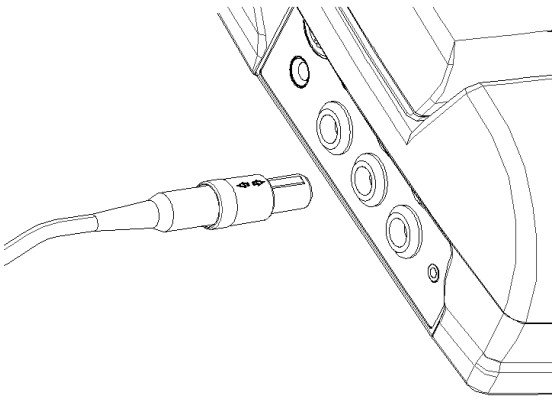
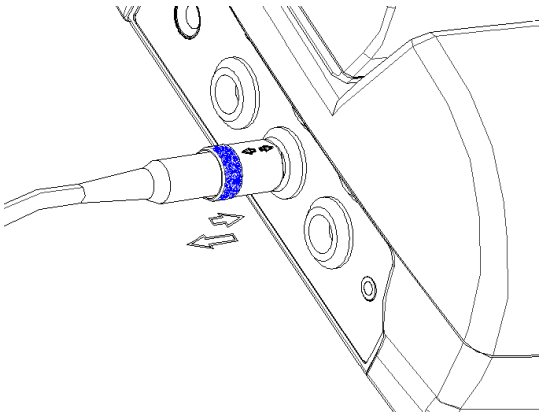


Figure 6-2 Disconnecting the transducer



When disconnecting a transducer, hold the afterbody of the transducer outshell (the shaded part shown in figure 6-2) with fingers and push it in slightly, then pull it out. Refer to figure 6-2.

6.7 Adjusting Volume

The monitor automatically detects which channel the ultrasound transducer is connected to. The corresponding volume adjustment key of this channel displays  , indicating the FH sound is

coming out from this channel, for example: 

; while the other one displays  , for example: 

. Press the **CHANNEL** key to switch the FH sound to the other channel.

Adjust the default monitoring volume:

The FH volume returns to the default level after the **START** key is pressed. This default level is adjustable. To change this level,

1 Select the setup key  on the main interface.
2 Select **Start Monitor** > **Volume**.
3 Select the volume from 0~9; the step is 1 and the default level is 3.
4 Select **OK**.

Adjust the real-time monitoring volume:

If the default volume level is not satisfactory during monitoring, you can adjust the real-time volume of each channel.

1 Select the volume adjustment key  on the main interface.
2 Rotate the control knob clockwise for one step, the volume increases by one level, there are ten levels for your choice; the green pane of the volume level indicator  increases by one at every two steps; rotate the knob anticlockwise to decrease the volume.
3 Press the knob again to confirm the volume level.

Adjust the key volume:

The volumes of pressing keys, rotating and pressing the control knob are also adjustable.

1 Select the setup key  on the main interface.
2 Select **Fetus** > **Beep Volume**.
3 Select **Low** (default), **High** or **OFF**.
4 Select **OK**.

Chapter 7 Understanding Measurement Results

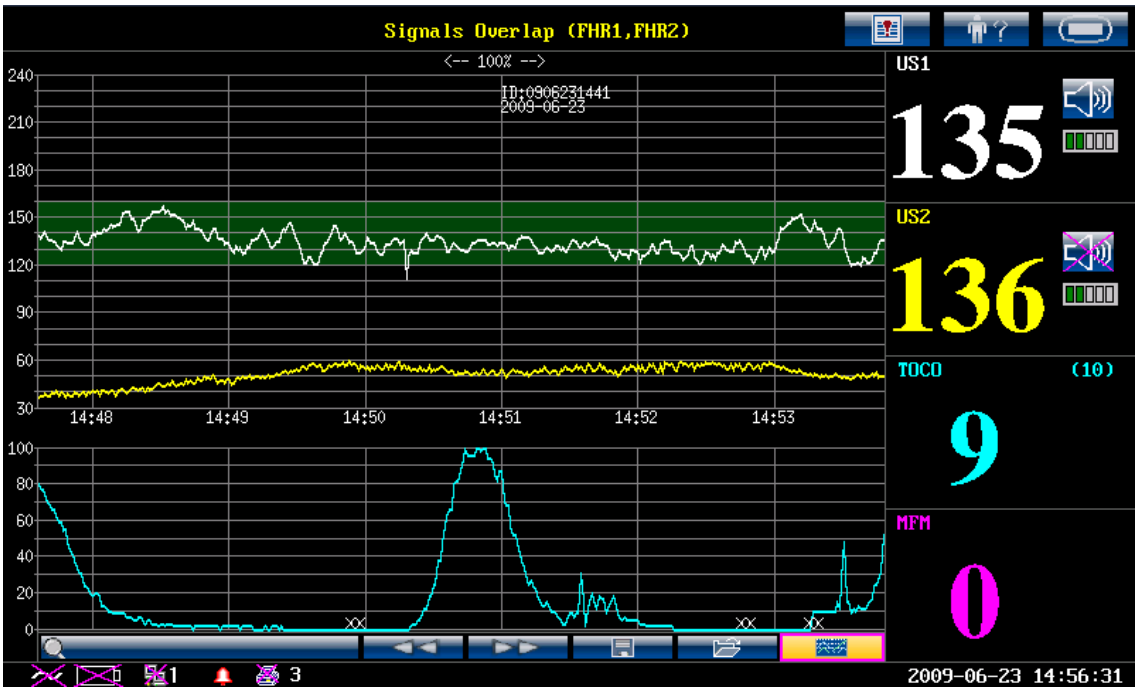


Figure 7-1 F6 screen display

7.1 Traces

⚠**WARNING**⚠**:** Due to the LCD size, resolution and system settings, the traces displayed on the screen may look different from the recorder printout. Take the printout as criterion when making diagnoses.

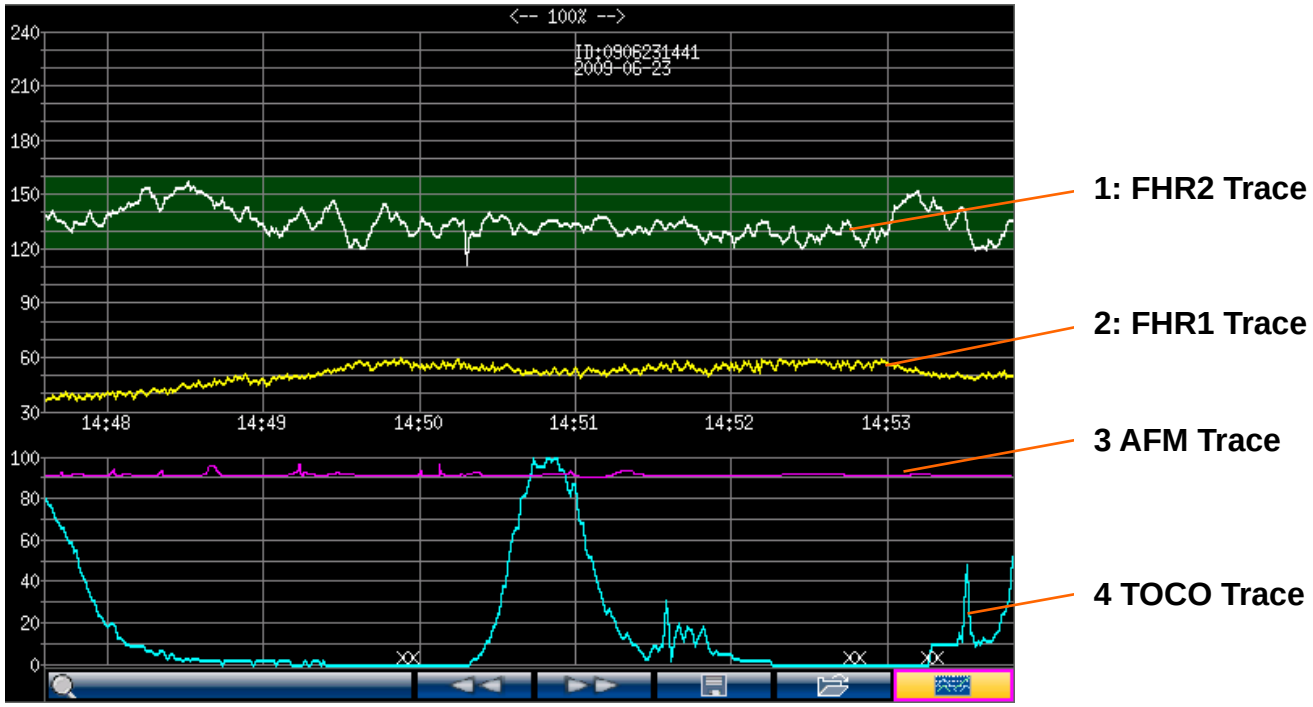


Figure 7-2 Traces

During monitoring or reviewing, the trace window displays four traces at most: FHR1 trace, FHR2 trace (dual configuration), AFM trace and TOCO trace.

FHR1/FHR2 trace

The y-axis of the trace indicates the numerics of FHR. The range is 30 bpm ~ 240 bpm (American standard) or 50 bpm ~ 210 bmp (International standard).

AFM trace

The y-axis indicates the scope of fetal movement.

NOTE: The AFM trace is only for reference, please take the MFM marks as criterion.

TOCO trace

The y-axis indicates the numeric of TOCO. The range is 0% ~ 100%.

Besides, some other symbols appear among the traces:

➞	This symbol indicates the new monitoring starts.
↑	This symbol indicates a manual fetal movement, and it appears after the patient presses the FM marker when she feels a fetal movement.
↓	This symbol indicates the **MARK** key is pressed to record an event, such as the patient turning around, taking injection.
⋈	This symbol indicates the monitor is zeroed by pressing **AUTO ZERO** key.

7.1.1 Changing Time Scale

The fetal monitoring traces share the same time scale, which displays the time every two minutes. This scale is either in real time format or relative time format. Real time is the time of the monitor. Relative time records the elapsed time for the current monitoring.

To change this time format:

1 Select setup key  on the main interface.
2 Select **Date And Time** > **Time Scale**.
3 Select **Real Time** (default) or **Relative Time**.
4 Select **OK**.

NOTE: The real time contains only the hour and minute, but no second. As a result, the time scale may correspond to the 0 ~ 59th second of the system time. Do not mistake the time scale for the exact time.

7.1.2 Changing Trace Advancing Mode

Trace advances as time passes by when the monitor receives valid data. If no valid data is received, the screen will either advance with Auto or Valid. **Auto** means the screen keeps advancing as time passes by; **Valid** means the screen advances when valid data is received, and it will stop after no valid data has received for 30 seconds. It will advance again when valid data is received.

To change the screen advancing mode:

1 Select setup key  on the main interface.
2 Select **Fetus** > **Trace Advancing**.
3 Select **Auto** (default) or **Valid**.
4 Select **OK**.

7.2 Trace Control Tools

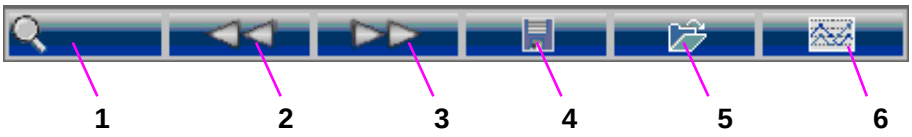
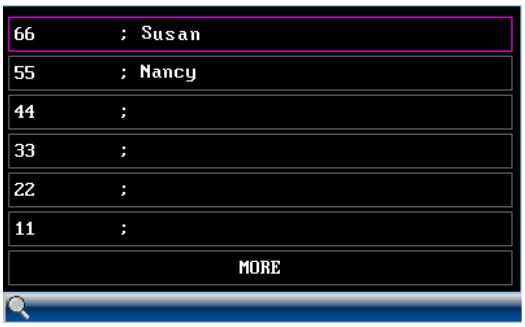


Figure 7-3 Trace control tools

1	Searching Key	2, 3	Reviewing Keys	4	Archiving Key
5	Archive Loading Key	6	Auto Measuring Key		

7.2.1 Searching for a Patient

The searching key  under the traces is used to search for a patient's data saved in the monitor.



Select this key to open the patient information list. It contains six sets of most recent patient's ID and name. Select the required item, and the main interface will switch to the most current data of this patient. If the patient is not in this list, select **MORE** and input the ID or name to search for the patient.

7.2.2 Reviewing

The reviewing keys  (backward key) and  (forward key) under the traces are used to review the traces.

Select the backward key to review the previous traces. The traces start to retreat. The amount of the progress symbol "<" on top of the traces indicates the retreating speed. Rotate the control knob anticlockwise to increase the speed until it reaches the maximum. Rotate the knob clockwise to decrease the speed until it reaches the minimum. Press the knob to pause.

Select the forward key to review the next traces. The traces start to advance. The amount of the progress symbol ">" on top of the traces indicates the advancing speed. Rotate the control knob clockwise to increase the speed until it reaches the maximum. Rotate the knob anticlockwise to decrease the speed until it reaches the minimum. Press the knob to pause.

When the reviewing is paused, the progress symbol turns to <--X%-->. If the **PRINT** key is pressed at this moment, the recorder will print the traces starting from the left edge of the screen at a high speed.

X% indicates the proportion of current traces positioned in the whole reviewable traces.

Move the cursor away from the trace control tools to return to the real-time main interface.

When reviewing the traces, the monitor does not stop. The FH sound and numerics are all real time information of the current patient.

⚠**CAUTION**⚠**:** You must pause before start printing. Printing in the process of playback might result in failed information on the paper.

7.2.3 Archive Managing

By default, the monitor saves the most recent 24-hour data in its memory. (Refer to section *9.1 Data Saving* for details.) However, when the memory is full, the anterior data would be cleared. There are possibilities that some important data is cleared. The monitor provides the archive storage to reduce these possibilities.

- Enabling/disabling archive storage

To enable or disable archive storage,

1 Select setup key  on the main interface.
2 Select **General Setup** > **Archive Storage**.
3 Select **ON** or **OFF** (default).
4 Select **OK**.

To archive the data of a patient, locate them using the reviewing keys first. When the data is displayed on the main interface, select the archiving key  . The data of this monitoring is stored in the monitor as a separate archive.

NOTE: If more than one patient is present on the main interface, the data of the patient on the right is archived.

The archives are stored in the long-term memory of the monitor. The capacity of the archive storage is 3,000 minutes. When the storage is full, you need to delete some archives before storing new data.

- Loading an archive

You can load an archive by selecting the archive opening key  on the main interface. A list of the archives pops up, including the time and duration of the monitoring, the patient's name and ID. Select the required one and then select **Load** to load the archive to the main interface. The loaded data starts from the left end of the screen. You can review the data by using reviewing keys.

Move the cursor away from the trace control tools to return to the real-time main interface.

- Deleting an archive

To delete an archive, select the archive opening key  on the main interface. Select the Archive and then choose **Delete** to delete the archive.

7.2.4 Auto Measuring

The auto measurement feature of the monitor provides baseline, acceleration peak and deceleration peak of a FHR trace.

NOTE: The auto measurement results are provided for reference only.

- Measuring the FHR1 trace,

Load the traces to the main interface by using reviewing keys and then select the auto measuring key  .

The following information is shown on the trace (figure 7-4):

- Baseline. A line is drawn in the central section of FHR1 trace, indicating FHR1 baseline.
- Acceleration peak. If the acceleration is larger than 15 bpm and lasts longer than 15 seconds, its amplitude and start time is marked above the peak in the format of +X[hh:mm:ss].
- Deceleration peak. If the deceleration is larger than 15 bpm and lasts longer than 20 seconds, its amplitude and start time is marked under the peak in the format of -X[hh:mm:ss].

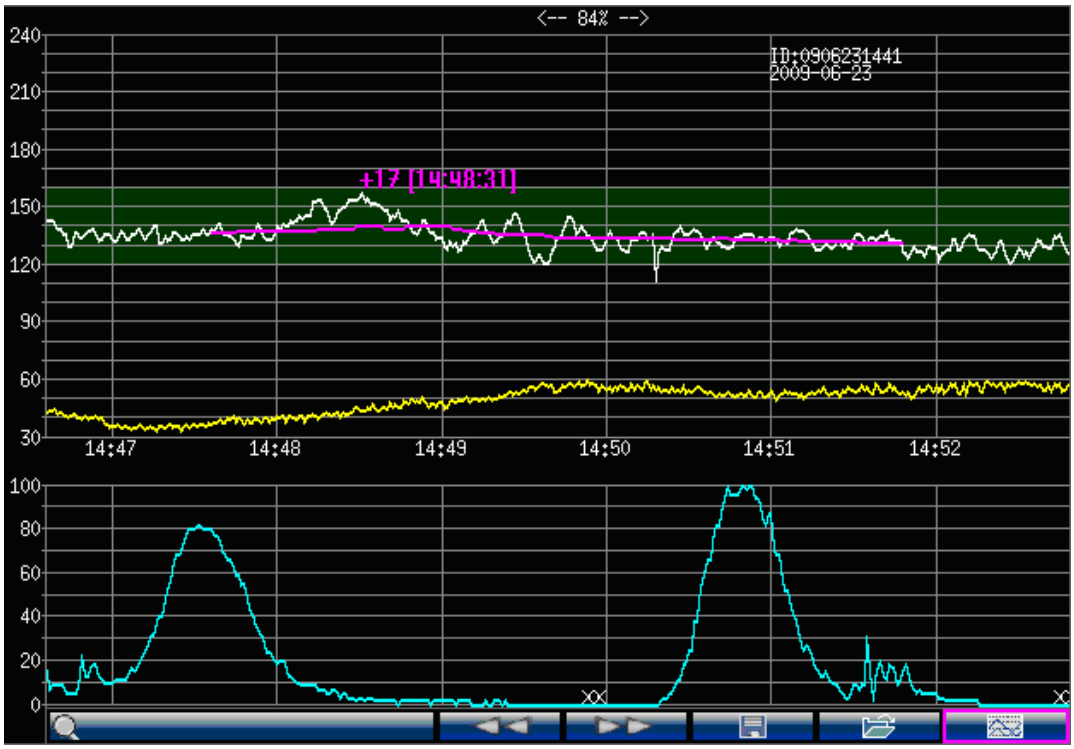


Figure 7-4 Auto measuring FHR1

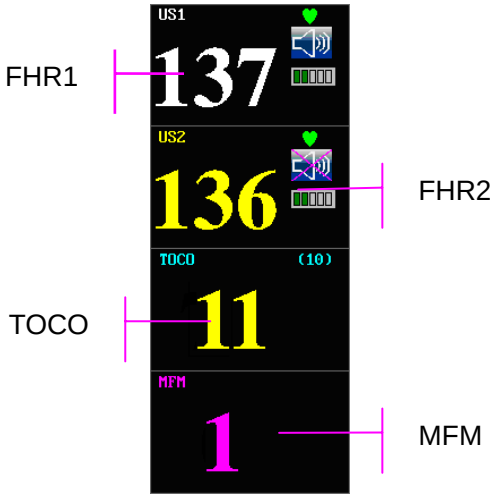
- Measuring the FHR2 trace,

Press the auto measuring key again, the monitor measures the FHR2 trace.

The auto measuring feature can only be applied to the reviewed FHR traces. The information disappears when you exit from the reviewing status.

7.3 Numerics

The numeric window includes FHR1, FHR2/DECG, TOCO/IUP and MFM.



The fetal monitoring values in the numeric window include FHR1 value, FHR2 value, TOCO value and MFM count:

FHR1 	: FH refreshing rate
	: FH sound volume adjusting key
	: FH sound volume indicator
	137: FHR1 measurement numeric. If the US1 socket is not connected with a US transducer, nothing displays here; if the transducer is connected but no monitoring is going on, it displays ---.
FHR2/DECG 	136: FHR2/DFHR measurement numeric. If the US2/DECG socket is not connected with a US transducer/DECG cable when switching on, it displays **OFF** but no numeric here; if the transducer/cable is connected but no monitoring is going on, it displays ---.
TOCO/IUP 	(10): UA baseline
	11: current UA measurement numeric
MFM 	1: MFM count

7.4 Alarm Messages

This table lists the alarm information that might appear during fetal monitoring, their respective causes and countermeasures.

Alarm Message	Cause	Countermeasure
Patient Alarm		
**FHR1 HIGH or ** FHR1 xxx > yyy, **FHR2 HIGH or ** FHR2 xxx > yyy	FHR1 or FHR2 measuring result (xxx) is higher than the set upper limit (yyy) over the alarm delay time.	Check if the alarm limits are suitable; check the woman's condition.
**FHR1 LOW or ** FHR1 xxx < yyy, **FHR2 LOW or ** FHR2 xxx < yyy	FHR1 or FHR2 measuring result (xxx) is lower than the set lower limit (yyy) over the alarm delay time.	Check if the alarm limits are suitable; check the woman's condition.

Technical Alarm		
US1 UNPLUGGED or US2 UNPLUGGED	US transducer 1 or US transducer 2 is not well connected.	Check the connection of the transducer.
US1 SIGNAL LOSS or US2 SIGNAL LOSS	FHR1 or FHR2 signal is too weak for the system to analyze.	Check if the US transducer is aimed at the fetal heart; check if the alarm limits are suitable; check the woman's condition.
TOCO UNPLUGGED	TOCO transducer is not well connected.	Check the connection of the transducer.
Fetus EQUIP MALF	The fetus board can not communicate with the system successfully.	Restart the monitor and try again, contact the manufacturer if the connection still fails.
Battery Low	The battery power is too low to support further work of the monitor.	Connect the monitor to AC power supply.
Check Paper	There is no paper in the paper drawer or the drawer is open.	Load paper and/ or close the drawer.
Signals Overlap (FHR1, FHR2)	US transducer 1 and US transducer 2 are aimed at the same fetal heart; the signals overlap.	Adjust one of the US transducers until another fetal heart signal is detected.
Signals Overlap (FHR1, DFHR)	US transducer 1 is aimed at the fetus that the spiral electrode is attached to; the signals overlap.	Adjust the US transducer until another fetal heart signal is detected.
DECG LEADS OFF	The spiral electrode is not well connected.	Check the connection of the spiral electrode.
DECG UNPLUGGED	The DECG lead is not well connected to the monitor.	Check the connection of the DECG cable.
DECG SIGNAL LOSS	DECG signal is too weak for the system to analyze.	Check if the spiral electrode is well attached to the fetus; check the woman's condition.

Chapter 8 Fetal Monitoring

⚠WARNING⚠:

1) The monitor is not intended for use in intensive care units (ICU), operating rooms or for home use.
2) The monitor is not protected against defibrillation. Do not apply it during electro-surgery or MRI; otherwise it might result in harming the patient or the operator.
3) Always check if the alarm settings are appropriate for your patient before starting monitoring.

8.1 Confirming Fetal Life

Fetal monitoring with ultrasound or DECG can not differentiate a fetal heart rate signal source from a maternal heart rate source in all situations. These are some of the signal sources that might be taken as FHR signal source by mistake:

- High maternal heart rate signal.
- Maternal aorta or other large vessels signals.
- Electrical impulse from the maternal heart transmitted through a recently deceased fetus.
- Movement of the deceased fetus during or following maternal movement.

So you need to confirm fetal life by other means before starting to use the fetal monitor, such as using a fetoscope, stethoscope, Pinard stethoscope or obstetric ultrasonography.

8.2 Monitoring FHR with Ultrasound

The ultrasound monitoring is a method to obtain FHR on maternal abdominal wall. Place a US transducer (Ultrasound transducer) on maternal abdomen. It transmits low energy ultrasound wave to the fetal heart, and receives the echo signal.

8.2.1 Parts Required

1) US transducer 2) Aquasonic coupling gel 3) Belt

8.2.2 FHR Monitoring Procedure

1) Placing Transducer Belt

Place the transducer belts across the bed, ensuring that the belt will be around the abdomen when it is fastened. Lay the patient on the bed.

Alternatively, the patient can take a sitting position. Arrange the belt around her abdomen.

2) Acquiring FH Signal

Search for the location of the fetal heart using a stethoscope or a fetoscope.

Apply a certain amount of acoustic gel on the transducer and move it slowly around the fetus site until a clear characteristic hoof-beat sound of the fetal heart is heard. Refer to figure 8-1 for the transducer position.

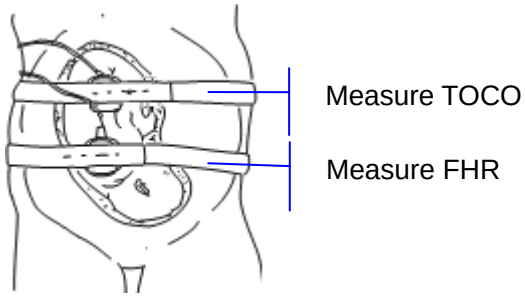


Figure 8-1 Positioning transducers (single fetus)

3) Fixing the Transducer

Wrap the abdomen with the belt over the transducer. Fix the transducer by pushing its buckle through the overlapping section of the belt.

Make sure the belt fits the patient snugly but comfortably. Meanwhile, fetus heart beat sound is heard; the FHR trace and numeric are displayed on the screen.

NOTES:

1) Do not mistake the high maternal heart rate for fetal heart rate. The fetal pulse can be distinguished from the maternal pulse by feeling the mother's pulse during the examination.
2) The best quality records will only be obtained if the probe is placed in the optimum position.
3) Positions with strong placental sounds or umbilical blood flow sound should be avoided.
4) If the fetus is in the cephalic position and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus. During monitoring, the pregnant woman's prolonged lying in the supine position should be avoided owing to the possibility of supine hypotension. Sitting up or lateral positions are preferable and may be more comfortable.
5) It is impossible to examine FHR unless an audible fetal heart signal is detected.

8.2.3 Switching FHR Alarm On or Off

Always check if the alarm settings are appropriate for your patient before starting a monitoring.

You can choose to switch the FHR alarm on or off. If the fetal heart alarm is switched off, the monitor will no longer give any audible or visual warning for this monitoring item.

1 Select setup key  on the main interface.
2 Select **Alarm > FHR1** or **FHR2 > Alarm**.
3 Select **ON** (default) or **OFF**.
4 Select **OK**.

If FHR1 or FHR2 alarm is switched off, an alarm switched-off symbol appears in the numeric window. For example:



⚠**WARNING**⚠**:** Do not switch the alarm off for the condition where the patient's safety maybe endangered.

8.2.4 Changing FHR Alarm Limits

You can change the FHR alarm limits. The alarm limits you set determine the conditions that trigger the alarm.

1 Select setup key  on the main interface.
2 Select **Alarm > FHR1** or **FHR2**.
3 Select a value from 50 ~ 205 for **Lower Limit**.
4 Select a value from 55 ~ 210 for **Upper Limit**.
5 Select **OK**.

8.2.5 Changing FHR Alarm Delay

You can change the FHR alarm delay. The alarm delay indicates how long the measured result continues exceeding its limit before the alarm is triggered.

1 Select setup key  on the main interface.
2 Select **Alarm > FHR1** or **FHR2 > Alarm Delay**.
3 Select a value from 0 ~ 300.
4 Select **OK**.

8.3 Monitoring FHR with DECG

8.3.1 Contraindications

The fetal spiral electrode can be used when amniotic membranes are adequately ruptured and sufficient cervical dilatation is ensured. The fetal electrode tip is designed to penetrate the epidermis of the fetus; therefore, trauma, hemorrhage and/or infection can occur. The electrode should be used with strict adherence to aseptic technique.

The fetal spiral electrode should not be applied to the fetal face, fontanels or genitalia.

Do not apply the fetal spiral electrode when placenta previa is present; when the mother has visible genital herpes lesions or reports symptoms of prodromal lesions; when the mother is HIV sero-positive; when mother is a confirmed carrier of hemophilia and the fetus is affected or of unknown status; or when it is not possible to identify fetal presenting part where application is being considered. This method is not recommended when fetus is extremely premature, or in the presence of a maternal infection such as Hepatitis B, Group B hemolytic strep, syphilis or gonorrhea, unless a clear benefit to the fetus or mother can be established.

8.3.2 Parts Required

1) DECG cable 2) Fetal spiral electrode 3) Disposable maternal attachment pad electrode

8.3.3 Preparing Patient's Skin Prior to Placing Electrodes

The skin is a poor conductor of electricity; therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

1) Shave hair from electrode sites, if necessary.
2) Wash the sites thoroughly with soap and water. (Do not use ether or pure alcohol, which will increase skin impedance)
3) Rub the skin briskly to increase capillary blood flow in the tissues.
4) Remove skin scurf and grease.

8.3.4 Directions for Using Fetal Spiral Electrode

1 With the patient in the dorsal lithotomy position, perform a vaginal examination and clearly identify the fetal presenting part.

2 Remove the spiral electrode from the package; leave the electrode wires locked in the handle notch.

3 Gently bend the guide tube to the desired angle.

4 Hold the drive handle, ensure the spiral electrode is retracted about one inch (2.5 cm) from the distal end of the guide tube.

5 Place the guide tube firmly against the identified presenting part.

6 Maintain pressure against the fetal presenting part with guide and drive tubes. Rotate the drive tube by rotating the drive handle clockwise until gentle resistance is encountered. Resistance to further rotation and recoil of the drive handle indicates that the spiral electrode is well attached to the fetus.

7 Release the electrode wires from the handle notch and straighten them. Slide the drive and guide tubes off the electrode wires.

8 Insert the safety cap into DECG cable.

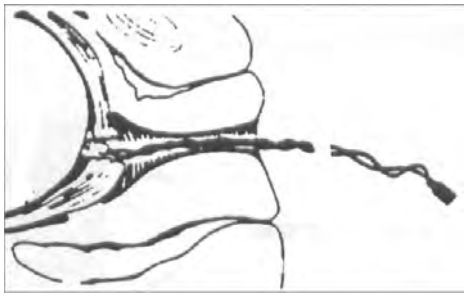


Figure 8-2 The well attached fetal spiral electrode

8.3.5 DECG Monitoring Procedure

1 Perform a vaginal examination to identify the fetal presenting part.

2 Prepare the patient's skin using the procedures described in section *8.3.3 Preparing the Patient's Skin Prior to Placing Electrodes.*

3 Attach the fetal spiral electrode to the fetal presenting part using the procedures described in section *8.3.4 Directions for Using Fetal Spiral Electrode*.

4 Fix an attachment pad electrode to DECG cable.

5 Remove the film on the back of the electrode and place the electrode on maternal thigh; press it firmly in place.

6 Connect the fetal spiral electrode to the DECG cable.

7 Insert connector of DECG cable into the DECG socket of the monitor.

⚠**WARNING**⚠**:** Do not plug the fetal spiral electrode wire into the power socket.

CAUTION: Do not mistake the higher maternal heart rate for DECG.

NOTES:

1) If there is any doubt as to the presence of a fetal heart signal with ECG, check with the US transducer on the patient's abdomen or with a separate diagnostic instrument. The presence of an audible Doppler heart sound at a rate distinct from that of the maternal pulse is unequivocal evidence of the fetal life.
2) After the electrode is well attached, allow a few minutes for the electrode and fetal tissue to become stabilized. It is essential that the ECG signal electrode is in good contact with the fetal presenting part.

8.3.6 Detaching Fetal Spiral Electrode

To detach the fetal spiral electrode, rotate it counterclockwise until it is free from the fetal presenting part. Do not pull the electrode from the fetal skin forcefully.

Dispose of the used fetal spiral electrode in a proper way. Do not use it again.

8.4 Monitoring Twin FHRs

8.4.1 Monitoring Twins Externally

To monitor twin FHRs externally, you need to connect a US transducer to US1 socket and the second US transducer to US2 socket of the monitor. Follow the instructions described in Section *8.2 Monitoring FHR with Ultrasound* to acquire FHR signals for both channels. Press **CHANNEL** key to switch the FH sound from one channel to the other.

When the two US transducers are fixed, make sure FH sounds from both channels are clear, two FHR traces and two FHR numerics are displayed on the screen.

8.4.2 Monitoring Internally

Alternatively, you can monitor a FH using ultrasound externally, and monitor the second FH using DECG internally.

Connect the US transducer to US1 socket; connect DECG cable to DECG socket.

Monitor one twin with a US transducer using the procedures described in Section *8.2 Monitoring FHR with Ultrasound*.

Monitor the second twin with a DECG cable using the procedures described in Section *8.3 Monitoring FHR with DECG*.

CAUTION: The US transducer must be connected to US1 socket. If the US transducer connects to US2 socket while DECG cable is connected to DECG socket, the FHR trace and numeric from US2 will not be displayed.

8.4.3 Signals Overlap Verification (SOV)

When monitoring twins, there are possibilities that one twin's FHR signal is mistaken for the other one's signal. The monitor provides signals overlap verification (SOV) function to reduce these possibilities.

In the process of monitoring, if the SOV detects signals overlapping, an alarm message "Signals Overlap (FHR1, FHR2/DFHR)" will appear on the screen to warn you. Checking the patient and reposition of transducers might be needed.

8.4.4 Changing FHR2/DFHR Offset

In order to distinguish FHR1 trace from FHR2/DFHR trace, FHR2/DFHR offset is provided to help you separate the two traces by an offset of -20 bpm or +20 bpm.

To change the FHR2/DECG offset,

1 Select setup key  on the main interface.
2 Select **Recorder > FHR2 Offset**.
3 Select **-20 bpm** (default), **0 bpm** or **+20bpm**.
4 Select **OK**.

This preset FHR2/DFHR offset will be printed on the recorder paper every 10 minutes.

"FHR2/DFHR: -20bpm": the FHR2/DFHR trace is 20bpm lower than it really is.

"FHR2/DFHR: +20bpm": the FHR2/DFHR trace is 20bpm higher than it really is.

8.5 Monitoring Uterine Activity Externally

8.5.1 Parts Required

1) TOCO transducer 2) Belt

8.5.2 TOCO Monitoring Procedure

1) Placing Transducer Belt

Place the transducer belts across the bed, ensuring that the belt will be around the abdomen when it is fastened. Lay the patient on the bed.

Alternatively, the patient can take a sitting position. Arrange the belt around her abdomen.

2) Fixing the Transducer

Refer to figure 8-1 for the TOCO transducer position. Wipe any gel remaining on abdomen around this area.

Place the transducer on the patient's fundus to get optimum recording of uterine activity.

Wrap the abdomen with the belt over the transducer. Fix the transducer by pushing its buckle through the overlapping section of the belt. Make sure the belt fits the patient snugly but comfortably.

3) Adjusting the Numeric to Zero

Press the **AUTO ZERO** key to adjust the numeric to the baseline. Make sure this is not done during a contraction.

The uterine activity reading at this point should be 30 ~ 90. A flat-top aligned with 100 on the TOCO scale indicates the belt is too tight, and you need to adjust it.

Wipe off any gel presents on abdomen around this area.

NOTES:

1) Do not apply aquasonic coupling gel on a TOCO transducer or its contact area.
2) Check the function of the TOCO transducer by applying pressure on it to see if this is displayed on the screen.

8.5.3 Changing UA Baseline

You can change the UA baseline,

1 Select setup key  on the main interface.
2 Select **Fetus > UA Baseline**.
3 Select **5**, **10** (default), **15** or **20**.
4 Select **OK**.

NOTE: If your monitor has been configured with IUP, the baseline will be 10 and not adjustable.

8.6 Monitoring Uterine Activity Internally

8.6.1 Parts Required

1) Disposable intrauterine pressure catheter ACCU-TRACE™ IUPC ("IUPC" for short)
2) Reusable intrauterine pressure connecting cable ("connecting cable" for short)
3) Reusable intrauterine pressure cable ("IUP cable" for short)

8.6.2 Directions for Use of IUPC

Preparation

1) Gather supplies: ACCU-TRACE IUPC, reusable cable, and amnioinfusion supplies if needed.
2) Open the sterile ACCU-TRACE IUPC package.

Insertion

NOTE: This product is designed for use with the introducer.

3) Using aseptic technique, remove the catheter from the package.
4) Perform vaginal exam to ensure ruptured membranes and adequate dilation.
5) Advance the catheter tip to the cervical os along the examination hand, using the hand as a guide. Do not advance the introducer through the cervix.
6) Continue to gently advance the catheter tip through the cervical os and feed the catheter into the intra-amniotic cavity until the 45cm mark is at the introitus. If the 45cm mark is not clearly visible, stop advancing when the ● symbol on the catheter meets the introducer.

   NOTE: For easier insertion, do not twist the catheter in the introducer.
7) The IUPC may be spontaneously filled with amniotic fluid. This can be seen in the clear lumen of the catheter. The filter cap will prevent the amniotic fluid from leaking.
8) Slide the introducer out of the vagina along the catheter. When the introducer is completely out of the vagina, slide thumb between catheter and introducer tab, which will begin to separate the introducer from the catheter. (See figure 8-3)

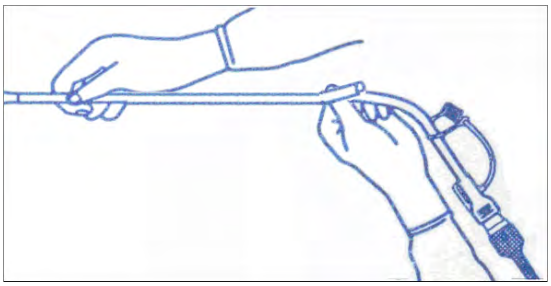


Figure 8-3 Separate the introducer

9) Anchor the catheter in place with one hand, and pull the introducer straight back off the catheter. (See figure 8-4)

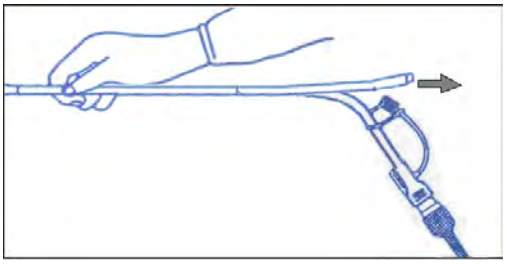


Figure 8-4 Remove the introducer

10) Remove the liner from the adhesive pad, and then adhere the pad to the patient's skin. Secure the catheter by placing the catheter attachment strap to the adhesive pad. (See Figure 8-5).

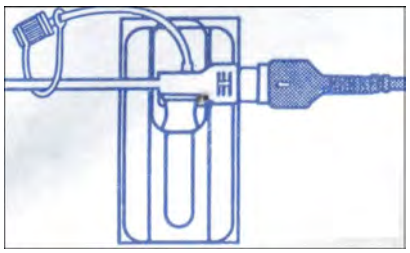


Figure 8-5 Secure the adhesive pad to mother

Rezeroing the System During Monitoring

1) With the catheter connected to the IUP cable, momentarily pressing the re-zero button on the pressure cable (See Figure 8-6). The green light on the cable will flash for five seconds.

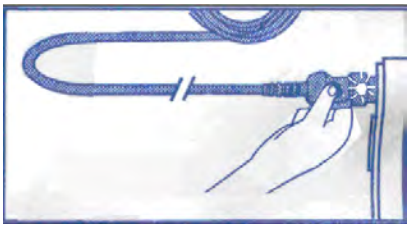


Figure 8-6 Rezeroing the system

2) During this period, adjust the monitor to zero by pressing **AUTO ZERO** key.

⚠WARNING⚠:

1) Before insertion, placental position should be confirmed, amniotic membranes are adequately ruptured and sufficient cervical dilatation is assured.
2) Try to insert the catheter opposite the placental site. Do not insert the introducer beyond the cervical OS. Use it with caution when uterine infection is present.
3) If resistance is met at any time during insertion, withdraw the catheter slightly and try at a different angle. Forced insertion may result in patient's discomfort or injury.

CAUTION:

1) Since procedures vary according to hospital needs/ preferences, it is the responsibility of the hospital staff to determine exact policies and procedures for both monitoring and amnioinfusion. The safe and effective use of the IUPC depends on the skill of the clinician who applies /uses it.
2) Read Directions For Use of IUPC prior to insertion. The Product has been sterilized by gamma radiation and is sterilized and non-pyrogenic unless package is broken or open. Do not re-sterilize it.

NOTE: Refer to the instruction on the package for more information about using the IUPC.

8.6.3 IUP Monitoring Procedure

1) Insert IUPC using the procedure described in section *8.6.2 Directions for Use of IUPC.*
2) Connect the IUPC to the IUP cable. (See figure 8-7)

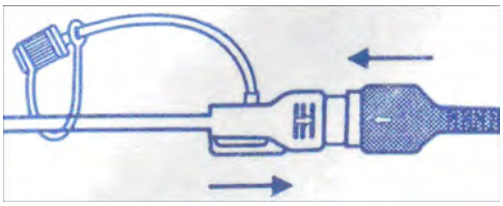


Figure 8-7 Connect catheter to pressure cable

3) Connect the IUP cable to the connecting cable. (They might have already been well connected in the package.)
4) Plug the connecting cable to the TOCO/IUP socket of the monitor.
5) Momentarily pressing the re-zero button on the IUP cable. The green light on the cable will flash for five seconds. During this period, zero the monitor by pressing the **AUTO ZERO** key. Make sure the display numeric and trace are both “0”.
6) Ask the mother to cough. A spike on the trace in response to the cough indicates proper positioning and function of the IUPC.
7) Wash timely during monitoring. A spike on the tracing will respond to the washing.

8.6.4 Checking Intrauterine Pressure Cable Function

To test an IUP cable’s function:

1) Disconnect the catheter from the cable. Insert the cable check plug into the catheter end of the cable. (See Figure 8-8).

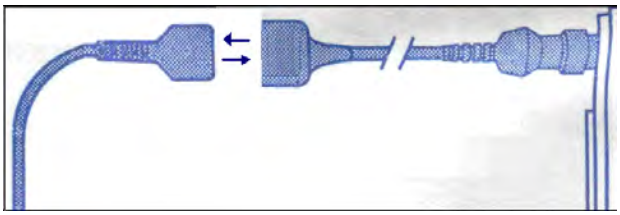


Figure 8-8 Test the pressure cable

2) Verify that the green light is continuously lit (no flashing).
3) If the light does not illuminate, replace the cable.

NOTE: If the light is flashing, verify that the cable check plug is inserted completely into the cable.

⚠**WARNING**⚠**:** The cable test function is not intended to check the accuracy of the system, only to confirm cable function.

8.7 Monitoring Fetal Movement

8.7.1 Auto Fetal Movement Monitoring (AFM)

During fetal heart monitoring with ultrasound, the fetal movement signals are also detected. The fetal movement signals differ from the Doppler heart rate signals in that they have larger extent and lower frequency. The larger extent is because of the bigger scope of moving areas (e.g., the fetal arms or legs); lower frequency is because of the lower velocity of the fetal movements compared with those of the fetal heart.

Only US1 channel can perform AFM. But be aware that when monitoring twins, the movements detected by US1 may also be caused by the second fetus's movement.

The movement of the fetus will be detected and displayed in the form of a trace on the screen and the recorder paper.

AFM monitoring can be switched off; its gain is adjustable.

8.7.2 Enabling or Disabling AFM Trace

The AFM trace on the screen and recorder paper can be enabled or disabled.

1 Select setup key  on the main interface.
2 Select **Fetus > AFM**.
3 Select **ON** or **OFF** (default)**.**
4 Select **OK**.

8.7.3 Changing AFM Gain

You can change the AFM gain. The AFM gain affects overall numeric and scope of the AFM trace.

1 Select setup key  on the main interface.
2 Select **Fetus > AFM Gain**.
3 Select **1**, **2**, **3** (default) or **4**.
4 Select **OK**.

8.7.4 Manual Fetal Movement Monitoring (MFM)

MFM result comes from the patient's feeling of fetal movement. The count will be displayed on the screen in MFM numeric area.

1) Insert the FM marker connector into the **MARK** socket on the monitor.

2) Let the patient hold the marker in hand; ask her to press the top key of it when a fetal

movement is felt. Continuous movements in 5 seconds are considered to be one movement and only press the key once.

8.8 Start Monitoring

After the **START** key is pressed, the monitor automatically zeroes the pressure, clears the MFM count and starts monitoring.

If the Auto start printing is disabled, press the **PRINT** key to start printing.

8.9 Inputting Maternal Information (Mat. Info)

8.9.1 Auto ID

After you press the **START** key, the system creates an auto-ID for the present patient. (if Mat. Info inputting is switched off.) The auto-ID consists of the date and time when the monitoring starts.

8.9.2 Changing Maternal Information

You can change the patient's information after the monitoring starts:

1 Select Mat. Info key  on the main interface.
2 Select **ID**.
3 Select the required number for patient's ID on the soft keyboard.
4 Select **ok**.
5 Select **Name**.
6 Select the required letter for patient's name on the soft keyboard.
7 Select **ok**.
8 Select **OK**.

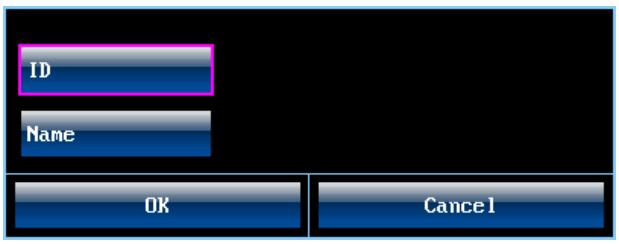


Figure 8-9 Mat. Info inputting menu

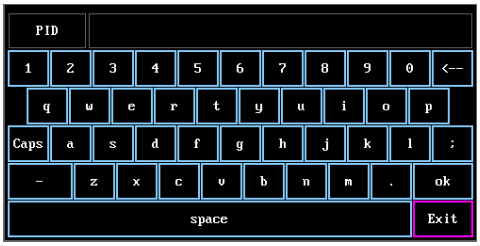


Figure 8-10 Soft keyboard

The monitoring does not stop when you change maternal information. After you select **OK** to exit, the new ID takes the place of the old one for this patient.

NOTES:

1) Pressing the START key separates two patients. The monitor only displays the most recent ID for the same patient.
2) If printing starts automatically with the monitoring, the first ID printed on the recorder paper will be the auto-ID. The new ID will be printed 10 minutes later.
3) You can only input English letters for the patient ID and name. The input ID appears on both the screen and the recorder paper. The name appears only in the archive list.

8.9.3 Switching Mat. Info Inputting On or Off

The **Mat. Info inputting** function allows the menu to pop up automatically after the **START** key is pressed. After you input the mother's information and exit from the menu, the monitoring starts immediately.

To switch the **Mat. Info Inputting** on or off:

1 Select setup key  on the main interface.
2 Select **Start Monitor** > **Mat. Info**.
3 Select **ON** or **OFF** (default).
4 Select **OK**.

Chapter 9 After Monitoring

9.1 Data Saving

The monitor automatically saves the data every 2 hours and prior to shutdown, including fetal monitoring traces and maternal information. The maximum capacity is 24-hour data.

When the monitor is switched on again, those data will be loaded. You can review them or print them at a high speed.

⚠**CAUTION**⚠**:** Switch off the monitor in a normal way as described in section *9.3 Switching Off*, otherwise the data that is not saved will be lost.

9.2 Completing Monitoring

After monitoring,

1) Remove transducers or electrodes from the patient; wipe the remaining gel off the patient and the transducer with a clean soft cloth or tissue.
2) Tear off the printed recorder paper along the perforation.

9.3 Switching Off

1) Press and hold the **POWER** switch for at least 3 seconds to switch off the monitor.
2) Unplug the power cord.

⚠**WARNING**⚠**:** Do not press the POWER switch continuously. Allow at least 10 seconds between switching the monitor on and off.

Chapter 10 Maintenance and Cleaning

10.1 Maintenance

10.1.1 Maintaining Inspection

(1) Visual Inspection

Prior to using the monitor every time, do the following inspections:

- Check the monitor and accessories to see if there is any visible evidence of damage that may affect patient safety. Pay special attention to the cracks on the transducers and cables before immersing them into conductive fluid.
- Check all the outer cables, power socket and power cables.
- Check if the monitor functions properly.

If any damage is detected, stop using the monitor on the patient. Replace the damage part(s) or contact the manufacturer for service before reusing it.

(2) Routine Inspection

The overall check of the monitor, including safety check and function check, should be performed by qualified personnel every 6 to 12 months, and each time after service.

The equipment should undergo periodic safety testing to ensure proper patient isolation from leakage currents. This should include leakage current measurement and insulation testing. The recommended testing interval is once a year or as specified in the institution's test and inspection protocol.

(3) Mechanical Inspection

Make sure all exposed screws are tight.

Check the external cables for splits, cracks or signs of twisting.

Replace any cable that shows serious damage.

Pay particular attention to the supply socket.

⚠**WARNING**⚠**:** Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

10.1.2 Maintenance of Monitor

Keep the exterior surface of the monitor clean, free of dust and dirt.

The gathering of dew on the screen may occur with abrupt temperature or humidity changes. A

table environment is recommended.

Scratching and damaging the screen should be avoided.

10.1.3 Maintenance of Transducers

Keep the transducers in a dry environment, where the temperature had better be lower than 45°C.

Gel must be wiped from the US transducer after use. These precautions will prolong the life of the transducer.

Although transducers are designed for durability, they should be handled with care. Rough handling could damage the cover, piezoelectric crystals and mechanical movement. Contacting the transducers with hard or sharp objects should be avoided. Do not excessively flex the cables.

10.1.4 Storage of Recorder Paper

When storing recorder paper (including used paper with traces):

Do not store in plastic envelopes.

Do not leave exposed to direct sunlight or ultraviolet light.

Do not exceed a storage temperature of 40 ºC (104 ºF).

Do not exceed a relative humidity of 80%.

Storage conditions outside these limits may distort the paper and adversely affect the accuracy of grid lines or make the trace unreadable.

10.1.5 Cleaning of Recorder

The recorder platen, thermal print head and paper sensing mechanism must be cleaned at least once a year or when needed (when traces become faint).

To do this:

1) Clean the recorder platen with a lint-free cloth dampened in soap/ water solution.

2) Wipe the thermal array using a cotton swab moistened with 70% Isopropyl alcohol-based solution.

3) Check that the paper sensing mechanism is free of dust.

⚠**WARNING**⚠**:** Only use the recorder paper provided by the manufacturer, or it may damage the recorder. This kind of damage is not covered by warranty.

10.2 Cleaning

In order to avoid infection, clean and disinfect the monitor and accessories after each use.

10.2.1 Cleaning of Monitor

Regular cleaning of the monitor enclosure and the screen is strongly recommended.

The solutions recommended for monitor cleaning are: soft soap water, Tensides, Ethylate and Acetaldehyde.

⚠**WARNING**⚠**:** Unplug the monitor from the AC power source and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.

Clean the monitor enclosure with soft cloth and diluent non-caustic detergents recommended above.

Clean the screen with a dry soft cloth.

CAUTION:

1) Although the monitor is chemically resistant to most common hospital cleaners and non-caustic detergents, different cleaners are not recommended and may stain the monitor.
2) Many cleansers must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the monitor.
3) Do not use strong solvent, for example, acetone.
4) Never use an abrasive such as steel wool or metal polish.
5) Do not allow any liquid to enter the product, and do not immerse any part of the monitor into any liquid.
6) Avoid pouring liquids on the monitor while cleaning.
7) Do not remain any cleaning solution on the surface of the monitor.

NOTES:

1) The monitor surface can be cleaned with hospital-grade ethanol and dried in air or with crisp and clean cloth.
2) The manufacturer has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

10.2.2 Cleaning of Accessories

(1) Cleaning of Transducers

Follow these steps to clean the US transducer, TOCO transducer and IUP cable:

1) Wipe them with a soft cloth dampened in cleaning solution;
2) Clean them with a soft cloth dampened in water;
3) Air-dry them or wipe the remaining moisture with a soft dry cloth.

The recommended cleansers for accessories are listed below:

Accessory	Cleansers
Ultrasound Transducer TOCO Transducer	BURATON LIQUID MIKROZID ETHANOL 70% SPORACIDIN CIDEX
DECG Leads	Mild alcohol-free soap water
IUP Cable	Mild alcohol-free soap water

CAUTION:

1) Be sure the temperature of cleaning solutions does not exceed 45 ºC (113 ºF).
2) Do not immerse them in any liquid.
3) Only clean the outer surface of the connectors, make sure no liquid goes into the connector.
4) After cleaning, no remaining cleanser is allowed on the surface.

(2) Cleaning of Belt

Wash soiled belts with soap and water. The water temperature must not exceed 60 ºC (140 ºF).

10.3 Disinfecting

Clean the equipment before disinfecting.

The table below lists the allowed disinfectant bases:

Type	Base
Instrument Disinfectant	Glutaraldehyde up to 3.6%
Surface Disinfectant	Ethanol 1- and 2- Propanol

CAUTION:

1) Do not use any disinfectant containing additional active ingredients other than those listed.
2) Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible density.
3) Do not immerse any part of the monitor or any accessory into liquid.
4) After disinfection, no remaining disinfectant is allowed on the surface.
5) Check if the monitor and accessories are in good condition. If any aging or damage is detected, replace the damage part(s) or contact the manufacturer for service before reusing them.

NOTE: The manufacturer has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

10.4 Sterilizing

Do not sterilize the monitor or the accessories, unless this is necessary according to your hospital regulation.

Chapter 11 Warranty and After-Sales Service

11.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period. The warranty period begins on the date the products are shipped to distributors.

The warranty is void in cases of:

a) damage caused by handling during shipping.
b) subsequent damage caused by improper use or maintenance.
c) damage caused by alteration or repair by anyone not authorized by EDAN.
d) damage caused by accidents.
e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

11.2 Service Policy

All repairs on products must be performed or approved by EDAN. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair shall be exclusively be performed by EDAN certified service personnel.

If the product fails to function properly - or if you need assistance, service, or spare parts - contact EDAN's service center. A representative will assist you troubleshooting the problem and will make every effort to solve it over the phone or Email, avoiding potential unnecessary returns.

In case a return can not be avoided, the representative will record all necessary information and will provide a Return Material Authorization (RMA) form that includes the appropriate return address and instructions. An RMA form must be obtained prior to any return.

Freight policy:

Under warranty: the service claimer is responsible for freight & insurance charges when a return is shipped to EDAN for service including custom charges. EDAN is responsible for freight, insurance & custom charges from EDAN to service claimer.

Out of warranty: the service claimer is responsible for any freight, insurance & custom charges for product.

Contact information:

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Appendix 1 Product Specifications

A1.1 Monitor

Physical Characteristics	**Dimensions:** 347mm x 330mm x 126mm **Weight:** Approx. 6 kg
Safety	**Comply with:** IEC 60601-1:1988+A1+A2, EN 60601-1:1990+A1+A2, IEC/EN 61157, IEC/EN 60601-2-37, IEC/EN 60601-1-2:2001+A1 **Anti-electric Shock Type:** Class I equipment with internal power supply **Anti-electric Shock Degree:** FHR1, FHR2, TOCO, FM, FS B IUP BF DECG CF **Degree of Protection against Harmful Ingress of Water:** Ordinary equipment (sealed equipment without liquid proof) **Degree of Safety in Presence of Flammable Gases:** Equipment not suitable for use in presence of flammable gases **Disinfection/Sterilizing Method:** Refer to this user manual for details **EMC:** Group I Class A **Working System:** Continuous running equipment **Earth Leakage Current (Limit):** N.C. 500μA S.F.C. 1000μA **Enclosure Leakage Current (Limit):** N.C. 100μA S.F.C. 500μA **Patient Leakage Current (Limit):** N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA **Patient Auxiliary Current (Limit):** N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
Power Supply	Operating Voltage: 100V-240V~ Operating Frequency: 50Hz/60Hz Input Power: 110VA Battery: 14.8V/4400mAh (Lithium-ion Battery)

Environment	**Monitor**	**Working** Temperature: +5 ºC ~ +40 ºC (+41 ºF ~ +104 ºF) Relative Humidity: 25% ~ 80% (non-condensing) Atmospheric Pressure: 860hPa ~ 1060hPa **Transport and Storage** Temperature: -20 ºC ~ +55 ºC (-4ºF ~ +131 ºF) Relative Humidity: 25% ~ 93% (non-condensing) Atmospheric Pressure: 700hPa ~ 1060hPa
	Transducers	**Working** Temperature: 0 ºC ~ +40 ºC (+32 ºF ~ +104 ºF) Relative Humidity: < 95% @ +40 ºC (+104 ºF) Altitude: -500m ~ 3000m **Transport and Storage** Temperature: -40 ºC ~ +60 ºC (-40ºF ~ +140 ºF) Relative Humidity: < 90% @ +60 ºC (+140 ºF) Altitude: -500m ~ 3000m
Display	LCD Size:	10.2” (Diagonal)
	Resolution:	800 × 3 (RGB) × 480
	Display Mode:	Normally white, Transmissive
	Pixel Pitch:	0.0925 mm(W) × 0.276 mm (H)
	Active Area:	222.0 mm(W) × 132.48 mm (H)
	Module Size:	235.0 mm(W) × 145.8 mm(H) × 6.1mm(D)
	Surface treatment:	Anti-glare
	Color Arrangement:	RGB-Stripe
	Interface:	Digital
	Viewing angle:	+/- 65° Horizontal, 45°/-65° Vertical
	Response Time:	TrR = 15ms (typ.) / TrD = 20ms (Typ)
	Contrast Ratio:	300:1 (Typ.)
	Brightness:	350 cd/m2 (Typ.)
	Backlight power consumption:	4.098W (Typ.)
	Panel power consumption:	250mW (Typ.)
	Weight:	332g ± 10%
Recorder	Paper:	Z-fold, thermosensitive (compatible with GE and PHILIPS recorder papers)
	Paper width:	152mm (GE), 150mm (PHILIPS)
	Effective printing width:	110mm (American Standard) 120mm (International Standard)
	FHR printout width:	70mm (American Standard) 80mm (International Standard)

	FHR scaling: 30bpm/cm (American Standard) 20bpm/cm (International Standard) TOCO printout width: 40mm TOCO scaling: 25%/cm Printing speed: Standard Speed (Real-Time Traces): 1 cm/min, 2 cm/min, 3 cm/min Fast Print Speed (Stored Traces): Up to 25mm/sec Accuracy of data: ± 5% (X axis) Accuracy of data: ± 1% (Y axis) Resolution: 8 dots/mm Record Information: FHR1 trace/mark, FHR2/DECG trace/mark, TOCO/IUP trace, AFM trace, fetal movement mark, event mark, AUTO-zero symbol, date, time, printing speed, ID and FHR2 Offset etc.
Memory	Auto data saving: 24-hour data Archive storage: 3,000-minute data
Signal Interface	DB9 network interface, RJ45 interface
Ultrasound	Technique: Ultrasound Pulse Doppler with autocorrelation Mode: PW Doppler Mode Pulse Repetition Rate: 2 KHz Pulse Duration: 92 μs Ultrasound Frequency: (1.0±10%) MHz p- < 1 MPa I_{ob} < 10 mW/cm^2 I_{spta} < 100 mW/cm^2 FHR Measurement Range: 50 bpm ~ 240 bpm Resolution: 1 bpm Accuracy: ±2 bpm Earth Leakage Current: < 10 uA @ 264 VAC applied to transducer Dielectric Strength: > 4000Vrms ISATA@ the transducer face: 1.865 mW/cm^2 Entrance beam dimensions: 6.08 cm^2 Measurement uncertainties for ISATA: ±26.6% Measurement uncertainties for ultrasonic power: ±26.6% Global Maximum Value: MI = 0.029, $I_{SPTA.3}$ = 2.77(mW/cm^2) $I_{SPPA.3}$ = 10 (mW/cm^2)

DECG	Technique: Peak-peak detection technique DFHR Measurement Range: 30bpm ~ 240bpm Resolution: 1bpm Accuracy: ±1bpm Input Impedance: > 10M (Differential, DC50/60Hz) Input Impedance: > 20M (Common Mode) CMRR: > 110dB Noise: < 4μVp Skin Voltage Tolerance: ±500mV Fetal Input Voltage Current: 20μVp-3mVp
TOCO	TOCO Range: 0% ~ 100%, Sensitivity: 3.7μV/V/g Non-linear Error: 10% Resolution: 1% Zero Mode: Automatic/ Manual Dielectric Strength: > 4000Vrms
IUP	Pressure Range: 0 ~ 100mmHg Sensitivity: 5μV/V/mmHg Non-linear Error: ± 3mmHg Resolution: 1% Zero Mode: Automatic / Manual
AFM	Technique: Pulsed Doppler ultrasound Range: 0 ~ 100% Resolution: 1%
Marking	Manual fetal movement mark

A1.2 Low Output Summary Table

Low Output Summary Table

(for systems with no transducers having global maximum index values exceeding 1.0)

System: F6 Fetal & maternal Monitor

Transducer Model	$I_{spta.3}$ (mW/cm^2)	TI Type	TI Value	MI	$Ipa.3@MI_{max}$ (W/cm^2)
PW1.0MHz	2.77	TIS	0.055	0.029	0.01
		TIB	0.629		

A1.3 Transducers and Cables

Ultrasound Transducer	Weight: 190g Cable Length: 2.5m Dimension: 88mm × 35mm
TOCO Transducer	Weight: 180g Cable Length: 2.5m Dimension: 88mm × 35mm
Remote Event Marker	Length: 2.5m Weight: 56g

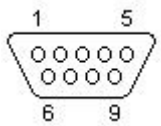
A1.4 Rechargeable Lithium-ion Battery

Type	Rechargeable Lithium-ion Battery
Continual Working Time	2h ~ 4h (depending on the configuration)
Necessary Charge Time	9h ~ 10h
Nominal Capacity	4400mAh
Nominal Voltage	14.8V
Charge Mode	Constant current/ constant voltage
Charge Current (Standard)	$0.2C_5A$ (800mA)
Charge Voltage (Standard)	(16.8 ± 0.1) V
Maximum Continuous Charge Current	2000mA
Storage Temperature	Short Term (within 1 month): -20 ºC ~ +60 ºC (-4 ºF ~ +140 ºF) Medium Term (within 3 months): -20 ºC ~ +45 ºC (-4 ºF ~ +113 ºF) Long Term (within 1 year): -20 ºC ~ +20 ºC (-4 ºF ~ +68 ºF) During storage, recharge the battery at least every six months.
Cycle Life	≥ 500 times

Appendix 2 Signal Input/Output Connector

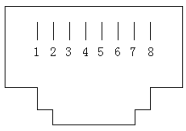
Accessory equipment connected to these interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Anybody who connects additional equipment to the signal input connector or signal output connector to configure a medical system must ensure that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, contact our technical service department or your local distributor.

DB9 Interface



Pin	Signal	Input/Output
1	+5V	Output
2	Rx	Input
3	Tx	Output
4	485EN	Input
5	0V Ref.	
6	TA	Output
7	TB	Output
8	RA	Input
9	RB	Input

RJ45 Interface



Pin	Signal	Input/Output
1	TD+	Output
2	TD-	Output
3	RD+	Input
4	Reserved	
5	Reserved	
6	RD-	Input
7	Reserved	
8	Reserved	

Appendix 3 Troubleshooting

A3.1 No Display

Phenomenon	Possible Cause	Solution
Power indicator is off.	Power cable is loose.	Tighten the power cable.
	The fuse is blown.	Change the fuse.
	The battery runs out of power.	Connect to AC power supply.

A3.2 Noise

Phenomenon	Possible Cause	Solution
Noise	Too high volume setup.	Turn down the volume.
	Interfered by mobile phone or other interfering source.	Keep the interfering source far away from the monitor.

A3.3 Recorder Error

Phenomenon	Possible Cause	Solution
Paper jam	Wrong loading paper or paper is dampened.	Load paper correctly and keep paper from moist.
Recorder does not work.	The recorder is not started.	Press the **PRINT** key.
	Run out of paper.	Load paper.
	The paper drawer is not locked.	Slide the paper drawer in until both latches are locked in position.

A3.4 Trouble with Ultrasound FHR Monitoring

Phenomenon	Possible Cause	Solution
Inconstant trace / display	The pregnant woman is too fat.	Monitor FHR with DECG.
	Improper ultrasound transducer position.	Adjust the position of the transducer till the better signal is received.
	Loose belt.	Tighten the belt.
	Superfluous aquasonic coupling gel.	Wipe off superfluous aquasonic coupling gel.
	Frequent fetal movements.	Delay the monitoring.
	Maternal movement.	Request the patient to calm down and stay still.
	Inadequate aquasonic coupling gel.	Use recommended aquasonic coupling gel quantity.
Doubtful FHR	Record maternal heart rate wrongly.	Change the position of the ultrasound transducer.
	The transducer is not well placed in position, and the mixed noise has been recorded.	Adjust the position of the transducer.
Feint trace or no trace	Improper paper.	Use paper recommended by manufacturer
	The paper drawer is not locked.	Slide the paper drawer in until both latches are locked in position.
	Adjusting nuts of the print head are unbalanced.	Contact the manufacturer for service.

A3.5 Troubles with DECG FHR Monitoring

Symptom	Possible Cause	Solution
Inconstant trend Inconstant display	No ECG signal	Use a new spiral electrode
	Bad contact of reference electrode and patient	Use a new spiral electrode
Inconstant trend	The DECG cable has not been fixed firmly	Fix an attachment pad at the DECG cable.

A3.6 Troubles with Contractions Monitoring (External)

Phenomenon	Possible Cause	Solution
Bad trace quality or fluctuant TOCO baseline	The belt is too tight or too loose.	Adjust the belt.
	The belt has no elasticity.	Renew the belt.
	Maternal movement.	Request the patient to calm down and stay still.
	Frequent fetal movements.	Delay the monitoring.
Too high TOCO sensitivity (higher than 100 unit)	The body pressure from uterus to TOCO transducer is far higher than the average numeric.	Insure favorable contact for patient skin with TOCO transducer. Change the position of TOCO transducer, if necessary.

A3.7 Troubles with Monitoring Contractions (Internal)

Symptom	Possible Cause	Solution
No trend	The intrauterine catheter is jammed	Wash with disinfector
No pressure change when uterine contraction	"Dry" environment or the tip of intrauterine catheter is placed extraovularly	Wash with disinfector or change the position of transducer
Only see the IUP peak but no baseline	Zero adjustment is wrong	Zero the system
The trend is a beeline	The connector failure.	Move or contact catheter. If trend no fluctuation, change intrauterine cable.

A3.8 Blown Fuses

⚠**WARNING**⚠**:** Switch off the monitor and unplug it before changing the fuse.

Replace the fuse when it is blown.

The two fuses of the monitor are located on the bottom panel, their specifications are:

Size: Φ5mm*20mm; Model: T1.6AL 250V.

To replace a fuse:

3) Fold the LCD display completely flat.
4) Carefully place the monitor upside down on a flat surface covered with cloth or other protecting pad.
5) With a flat-head screw driver, push the fuse in for about 1 mm and then unscrew it anticlockwise.
6) Remove the old fuse and replace it with a new fuse that is supplied by the manufacturer or of the same specifications.
7) Push the new fuse into the socket for about 1 mm and then screw it clockwise back in position.

Appendix 4 Abbreviation

The abbreviations used in this manual and their full names are listed below:

Abbreviation	Full Name
AC	Alternative Current
AFM	Automatic Fetal Movement [Detection]
BPM	Beat(s) Per Minute
CTG	Cardiotocography
DC	Direct Current
DECG	Direct ECG
DFHR	Direct FHR
ECG	Electrocardiogram
FH	Fetal Heart
FHR	Fetal Heart Rate
FM	Fetal Movement
FS	Fetal Stimulator
ICU	Intensive Care Unit
ID	Identity
IUP	Intra-Uterine Pressure
IUPC	Intra-Uterine Pressure Catheter
LCD	Liquid Crystal Display
MFM	Manual Fetal Movement [Detection]
NST	Non Stress Test
SOV	Signals Overlap Verification
TOCO	Tocotonometer
UA	Uterine Activity [TOCO/IUP]
US	Ultrasound [Transducer]

Appendix 5 EMC Information – Guidance and Manufacture's Declaration

A5.1 Electromagnetic Emissions – for all EQUIPMENT and SYSTEMS

<table>
<tr><th colspan="3">Guidance and manufacture's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The F6 Fetal & maternal Monitor is intended for use in the electromagnetic environment specified below. The customer of the user of the F6 Fetal & maternal Monitor should assure that it is used in such and environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td rowspan="4">The F6 Fetal & maternal Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class A</td><td rowspan="3">The F6 Fetal & maternal Monitor is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

A5.2 Electromagnetic Immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *F6 Fetal & maternal Monitor* is intended for use in the electromagnetic environment specified below. The customer or the user of *F6 Fetal & maternal Monitor* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ±2 kV line to ground	± 1 kV line to line ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz, 60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the F6 Fetal & maternal Monitor requires continued operation during power mains interruptions, it is recommended that the F6 Fetal & maternal Monitor be powered from an uninterruptible power supply or a battery.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

A5.3 Electromagnetic Immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The F6 Fetal & maternal Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of F6 Fetal & maternal Monitor should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 V_{rms}
150 kHz to 80 MHz

3 V/m
80 MHz to 2.5 GHz</td><td>$3V_{rms}$

3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the F6 Fetal & maternal Monitor including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a)] should be less than the compliance level in each frequency range.[b)]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
</table>

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *F6 Fetal & maternal Monitor* is used exceeds the applicable RF compliance level above, the *F6 Fetal & maternal Monitor* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *F6 Fetal & maternal Monitor*.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

A5.4 Recommended Separation Distance

Recommended separation distances between portable and mobile RF communications equipment and the *F6 Fetal & maternal Monitor*

The *F6 Fetal & maternal Monitor* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *F6 Fetal & maternal Monitor* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *F6 Fetal & maternal Monitor* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.37**	**0.37**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.7**	**3.7**	**7.3**
100	**12**	**12**	**23**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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